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2018-2019 ACA Litigation Review: Straining the Acronym Soup

Presented and prepared by:

CAITLYN FRANCOIS
Director of Public Policy
Medica
Minnetonka
2018 – 2019 ACA Litigation Review:
Straining the Acronym Soup

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Although this outline is intended to serve as an overview of the key federal litigation related to the insurance provisions of the Affordable Care Act, individuals wanting to know more about other ACA-related litigation, including pleadings and supporting documents, can access them on https://affordablecareactlitigation.com/.

This outline is accurate as of May 22, 2019.

I. Constitutionality of the ACA after the Tax Cuts and Jobs Act of 2017

In 2017, Congress attempted several times to repeal and replace the Affordable Care Act (“ACA”). In September 2017, Senate Majority Leader Mitch McConnell announced that the Senate would not be bringing the GOP-supported Graham-Cassidy legislation to vote before the end of the budget reconciliation period, thereby ending the ACA repeal and replace efforts in 2017. Shortly thereafter, Congress pivoted to enacting tax reform. Section 11081 of Tax Cuts and Jobs Act of 2017 amended 26 U.S.C. 5000A by “zeroing-out” the individual mandate percentages and financial penalties, effective January 1, 2019.

A. Texas v. United States

*Status:* On appeal to the Fifth Circuit Court of Appeals. Plaintiffs’ and the Administration’s briefs were due on May 1, 2019, and reply briefs are due May 22, 2019. The Administration requested an expedited oral argument, which was unopposed, positing that “prompt resolution of this case will help reduce uncertainty in the healthcare sector, and other areas affected by the Affordable Care Act.” Approving the DOJ’s request for an expedited oral argument, the Fifth Circuit will hear oral arguments in the case the week of July 8, 2019.

*Summary:* This case is a constitutional challenge, brought by Texas, nineteen other states, and two individual plaintiffs, on the validity of the ACA after Congress enacted the Tax Cuts and Jobs Act of 2017. The plaintiffs filed the lawsuit in the United States District Court of Northern Texas seeking emergency relief to enjoin the federal government from enforcing the ACA. The plaintiffs argued that after the 2017 Congress zeroed out the individual mandate penalty under Section 5000A(b) of the Internal Revenue Code, the individual mandate penalty could no longer be characterized as a tax, which was the Supreme Court’s saving interpretation in *National*  

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1 Patient Protection and Affordable Care Act, Public Law 111-148.
3 Id.
4 Public Law 115-97.
7 Wisconsin has withdrawn from the case.
8 See supra note 4.
Federation of Independent Businesses v. Sebelius. If true, the plaintiffs argued the ACA was no longer constitutional. Seventeen states, led by California, intervened in the lawsuit and alleged that the federal government would not adequately defend their position. The Administration agreed with the plaintiff states, but argued at the District Court that only the community rating, guaranteed issue, and preexisting condition protection provisions of the ACA should be held unconstitutional. The Administration requested that the District Court not issue any decision until after the conclusion of the 2019 open enrollment period.

On December 14, 2018, U.S. District Court Judge Reed O’Connor issued an order granting partial summary judgment to the plaintiff states. The Court found that the individual plaintiffs had standing to bring the challenge, because under the Fifth Circuit, standing can be established “where a plaintiff alleges that a federal statute or regulation ‘deters the exercise of his constitutional rights.’” The order declared the individual mandate with the zeroed-out penalty unconstitutional as the individual mandate “is no longer fairly readable as an exercise of Congress’s Tax Powers and continues to be unsustainable under Congress’s Interstate Commerce Power.” Judge O’Connor relied on the Supreme Court’s listing of the key characteristics of a tax in NFIB v. Sebelius:

The Supreme Court thus identified three basic criteria to conclude § 5000A could be viewed as an exercise of the Tax Power: (1) a payment is paid to the Treasury, (2) the payment amount is determined with reference to income and other familiar factors, and (3) the payment produces revenue for the Government. The Court found that “the Individual Mandate no longer ‘triggers a tax’ beginning in 2019. So long as the shared-responsibility payment is zero, the saving construction articulated in NFIB is inapplicable and the Individual Mandate cannot be upheld under Congress’ Tax Power.” The Court then turned to whether the individual mandate was sustainable under the Interstate Commerce Clause, but found that the “Individual Mandate now serves as a standalone command that continues to be unconstitutional under the Interstate Commerce Clause.”

Judge O’Connor also invalidated the remainder of the ACA as inseverable, holding that the 2010 Congress “memorialized that it knew the Individual Mandate was the ACA keystone. . . the Supreme Court stated repeatedly that it knew Congress knew that, . . . and knowing the Supreme Court knew what the 2010 Congress had known, the 2017 Congress did not repeal the Individual

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11 Id. at 585.
12 Id. at 595 (summarizing NFIB v. Sebelius, 567 U.S. at 563-64 (majority) (2012)).
13 Id. at 601.
14 Id. at 605.
15 Id. at 579.
Mandate and did not repeal § 18091.”

The Court later turned to the remaining four counts of the complaint and “because many everyday Americans would otherwise face great uncertainty during the pendency of appeal, the Court finds that the December 14, 2018 Order clearing the Individual Mandate unconstitutional and inseverable should be stayed.”

The intervernor defendant states and the Administration filed an appeal to the Fifth Circuit Court of Appeals in early January. On February 14, 2019, the U.S. House of Representatives intervened as a party on the appeal. Opening briefs were due March 25, 2019, and the Department of Justice sent a letter to the Fifth Circuit announcing its position that it agrees with the District Court’s decision.

Appellate briefs for the Administration, plaintiff states, and two individual plaintiffs were due May 1, 2019. The issues to before the Fifth Circuit include: (1) whether the individual plaintiffs have standing; (2) whether the plaintiff states have standing; (3) whether the ACA is constitutional after the zeroing out of the individual mandate penalty; and (4) if the individual mandate cannot be construed as a tax under Congress’ Tax Power, whether the remainder of the ACA is inseverable. The table below indicates how each of the parties have addressed the four issues in their appellate briefs:

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<th>Intervening States</th>
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**Implications:** The District Court’s ruling that the individual mandate could no longer be characterized as a tax, and the remaining provisions of the ACA are inseverable was stayed pending appeal to the Fifth Circuit, so the decision had no immediate effect on health insurance offerings. Regardless of the outcome at the Fifth Circuit, the case will likely be appealed to the U.S. Supreme Court. The U.S. Supreme Court may grant cert in mid-2020, with oral arguments

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in late 2020, and a decision by the end of June 2021, and we may experience what amounts to a re-litigation of *NFIB v. Sebelius*.

**B. Maryland v. United States**

*Status:* Dismissed without prejudice due to lack of standing.

*Summary:* As a bookend case to *Texas v. United States*, the State of Maryland filed a lawsuit on September 13, 2018, seeking a declaratory judgment and injunction that the ACA was constitutional and must be enforced. The state sought to “head off the myriad of serious harms that will fall the State and its residents if the Trump Administration . . . ceases [to] enforce[e] the ACA in whole or in part.” The defendants moved to dismiss the complaint for lack of subject matter jurisdiction and failure to state a claim, arguing that the State lacked standing because it asserted a speculative harm. Maryland alleged harm to its proprietary and financial interests, quasi-sovereign interests, and sovereign interests. The District Court sought supplemental briefing on the impact of the *Texas v. United States* decision on the Maryland’s standing. On February 1, 2019, the District Court dismissed the suit without prejudice on the basis that the injuries alleged by the state were speculative: “the State has not pointed to any actual threat by the President to terminate enforcement of the ACA,” and that the State’s suit “is tantamount to a request for an advisory opinion to thwart the possibility of the President deciding not to enforce the Act.”

*Implications:* Although the case was dismissed, Judge Hollander indicated that Maryland could revive its litigation if the claim becomes ripe for future review.

**II. ACA Premium Stabilization Programs and Affordability Programs**

The ACA included three programs intended to stabilize premiums in the individual and small group markets: transitional reinsurance, permanent risk adjustment, and temporary risk corridors. There are several federal lawsuits related to two of these programs: risk adjustment and risk corridors.

The purpose of the risk adjustment program is to reduce or eliminate the impact of risk selection by redistributing funds from plans with lower-risk enrollees to plans with higher-risk enrollees. According to the American Academy of Actuaries:

The [risk adjustment] program transfers money among insurers based on the risks of the people they enroll and the average premium collected within the state for all

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20 Id. at 294.
21 Id.
22 Id. at 316.
insurers. Insurers with a relatively healthier enrollee population contribute to a fund that makes payments to those insurers with a relatively sicker enrollee population. The risk adjustment program is designed to be revenue-neutral within each state. That is, transfer payments from insurers with a relatively healthier population equal transfer payments to insurers with a relatively sicker population.\textsuperscript{24}

The risk corridors program was intended to promote accurate premiums in the early years of implementation by discouraging individual market issuers from setting premiums too high to reduce uncertainty or too low to buy-up market share.\textsuperscript{25} Under the risk corridors program, the federal government would provide funding if a health plan’s losses exceeded a certain threshold, and a health plan would pay the federal government if its gains exceeded a certain threshold.\textsuperscript{26}

\textbf{A. Risk Adjustment}

New Mexico Health Connections, a New Mexico Co-Op health plan, filed two lawsuits alleging HHS did not follow the Administrative Procedures Act when adopting the use of the statewide average premium to maintain budget neutrality in the federal ACA risk adjustment program.

\textbf{Status}: On appeal to the Tenth Circuit Court of Appeals. New Mexico Health Connections filed a brief, which did not request oral arguments, on April 22, 2019. The Administration’s reply brief is due June 3, 2019.\textsuperscript{27}

\textbf{Summary}: This case involves a challenge to HHS’ policy of using a statewide average premium in its 2014-2018 risk adjustment regulations. Early in 2018, U.S. District Court Judge James Browning issued a decision setting aside and vacating that policy for the 2014-2018 benefit years because they agency failed to sufficiently explain its rationale and remanded the regulation back the agency to revisit. The judge in the New Mexico case previously indicated that HHS could


\textsuperscript{25} See supra note 23.

\textsuperscript{26} Research Brief: Design and Implementation Considerations of ACA Risk-Mitigation Programs, AM. ACAD. OF ACTUARIES available at https://www.actuary.org/sites/default/files/files/AAA-SOA_research_brief_on_3Rs_060412.pdf. The following is an excerpt from Congressional testimony: “If actual claims are within 3 percent of expected, insurers either keep the gains or bear the losses. If actual claims exceed expected claims by more than 3 percent, the federal government reimburses the insurer for 50 percent of the losses between 3 and 8 percent, and 80 percent of the losses exceeding 8 percent. If actual claims fall below expected claims by more than 3 percent, the insurer pays the federal government for 50 percent of the gains between 3 and 8 percent, and 80 percent of the gains exceeding 8 percent.” ObamaCare: Why the Need for an Insurance Company Bailout? Before the H. Comm. on Oversight and Gov’t Reform, 113th Cong. (2014) (statement of Cori E. Uccello, Am. Acad. Of Actuaries) available at https://www.actuary.org/sites/default/files/files/Risk_Corridors_Testimony_020514.pdf.

pursue rulemaking to explain its rationale for adopting the statewide average premium.\textsuperscript{28} This ruling came after a U.S. District Court of Massachusetts ruling that found that HHS acted within its authority in adopting the statewide average premium.\textsuperscript{29}

HHS filed a motion in March 2018 to alter or amend the judgment. A hearing was held in June, and HHS asked the court to use its discretion to remand the rule to HHS without vacating it, or to limit the impact to New Mexico. Shortly thereafter, HHS released a press statement that it would be delaying the 2017 risk adjustment payments and collection.\textsuperscript{30} On July 24, 2018, HHS released a final rule on 2017 risk adjustment program. HHS previously adopted the methodology for the 2019 risk adjustment program, and explained its rationale for adopting the statewide average premium.\textsuperscript{31} Judge Browning declined to alter or amended the original March 2018 judgment,\textsuperscript{32} and HHS appealed the decision to the Tenth Circuit Court of Appeals on December 14, 2018.\textsuperscript{33} In the meantime, HHS also released a proposed rule on the 2018 risk adjustment program.\textsuperscript{34}

Shortly after the release of the final rule on the 2017 risk adjustment program, New Mexico Health Connections filed a second lawsuit on August 13, 2018, alleging that the 2017 final rule also violated the Administrative Procedures Act.\textsuperscript{35} That case was reassigned to Judge Browning and is currently stayed. On November 2, 2018, the judge continued the stay of the case pending a further status report by the parties. On January 28, 2019, the parties filed a joint status report that include a request to stay proceedings until the appeal in the lawsuit challenging the 2014-2018 risk adjustment regulations is resolved. The Court has not responded.

New Mexico Health Connections filed its appellate brief to the Tenth Circuit on April 22, 2019.\textsuperscript{36} New Mexico Health Connections reasserts its argument: HHS was arbitrary and capricious in

\textsuperscript{28} “Nevertheless, HHS could have justified its promulgation of budget neutral regulations if it determined that budget neutrality was a worthy policy goal. HHS never made such a determination in the record, however, and the Court considers only the reasons that the agency actually gave and not the reasons that the agency might have given when determining agency action was arbitrary and capricious.” New Mexico Health Connections v. U.S.s Dep’t of Health & Human Servs., 312 F. Supp. 3d 1164 at 1205 (Feb. 28, 2018).
\textsuperscript{31} Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 83 Fed. Reg. 16930 at 16954 (Apr. 17, 2018).
\textsuperscript{34} Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit year; Proposed Rule, 83 Fed. Reg. 39644 (Aug. 10, 2018).
finalizing the regulations for the ACA risk adjustment program to use a statewide average premium
to maintain budget neutrality, and that vacating the regulations was the appropriate remedy.

**Implications:** The litigation opened questions about how health insurers were supposed to account
for expected, but not received, risk adjustment payments in their medical loss ratio reports, as well
as whether CMS would require health insurers to unwind the payments and collections made for
the 2014, 2015, and 2016 benefit years.

**B. Risk Corridors**

**Status:** The Supreme Court is reviewing a petition for a writ of certiorari in *Moda Health Plan
Inc. v. United States, 37* which is linked with *Maine Community Health Options v. United States
and Land of Lincoln Mutual Health Insurance Co. v. United States*. The issue is “whether Congress
can evade its unambiguous statutory promise to pay health insurers for losses already incurred
simply by enacting appropriations riders restricting the sources of funds available to satisfy the
government’s obligation.”38 Moda Health Plan, Blue Cross and Blue Shield of North Carolina,
Land of Lincoln, and Maine Community Health Options filed their petition on February 4, 2019;
the United States filed a brief in opposition on May 8, 2019.39 The insurers have one more
opportunity to respond before the Supreme Court consider whether or not to accept the appeal.40

**Summary:** The crux of the cases is whether Congress appropriated funds for making risk corridor
payments or could use other HHS funds to help pay for risk corridor payments. In December 2014,
Congress enacted an appropriations act for fiscal year 2015, and it included a provision that
expressly prohibited the use of additional HHS funds to pay for the risk corridors program:

> None of the funds made available by this Act from [CMS trust funds], or transferred
> from other accounts funded by this Act to the ‘Centers for Medicare and Medicaid
> Services—Program Management’ account, may be used for payments under
> section 1342(b)(1) of Public Law 111-148 [i.e., 42 U.S.C. 18062(b)(1)] (relating to
> risk corridors).41

Congress reenacted the same prohibition in the 2016 and 2017 appropriations.42

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18-1028).
38 Id. at i.
39 Brief for the United States in Opposition, Maine Community Health Options v. U.S., Moda Health Plan, Inc. v.
40 Katie Keith, *ACA Litigation Round-Up: Risk Corridors, CSRs, AHPs, and Short-Term Plans*, HEALTHAFFAIRS,
Several health insurers sued HHS for failing to make more than $12 billion in outstanding risk corridors payments. Health insurers sued in the Court of Federal Claims under the Tucker Act. In *Moda*, the Claims Court granted Moda partial summary judgment as to liability. Other similar suits in the Claims Court had mixed results. The Federal Circuit Court reversed the *Moda* decision on June 14, 2018, holding the statute created an obligation of the government to pay exchange participants the amount indicated by the statutory formula, but the Congressional appropriations bills repealed or suspended HHS’ obligation to make payments. The Federal Circuit Court found that no statement by the government evinced an intent to form a contract.

**Implications:** Due to the retroactive calculation of risk corridor payments, health insurers offering exchange coverage in the individual market were unable to account for Congress’ appropriation instructions in their product pricing. The results of any Supreme Court decision, if it grants cert, may have political implications, as noted by Timothy Jost: “There is a real problem as to the government’s willingness and ability to make good on its promises going forward.” Additional health insurers, not party the *Moda* or *Land of Lincoln* may have their opportunity for recover: Health Republic Insurance Company v. United States, a class action seeking recovery of risk corridor payments, was stayed pending a final decision in *Moda* and *Land of Lincoln*.

### C. Cost-Sharing Reductions

Cost-sharing reductions (“CSRs”) help reduce deductibles, copayments, coinsurance, and out-of-pocket maximums for lower-income qualified health plans enrollees. Section 1402 of the ACA requires qualified health plan issuers to provide CSRs to eligible low-income marketplace consumers. The federal government reimburses qualified health plan issuers in the individual market for the cost of providing CSRs.

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44 Id. at 1330.
45 Many insurers, including co-ops formed under the ACA, went out of business because of their inability to collect risk corridor payments. How the ACA ‘Risk Corridor’ Fallout is Hurting Health Care, KNOWLEDGE @ WHARTON, (Mar. 29, 2018), available at https://knowledge.wharton.upenn.edu/article/significance-risk-corridors-lawsuits/ (summarizing statements by Tim Jost).
46 Id.
49 45 CFR § 156.430(b)(1) (“A QHP issuer will receive periodic advance payments based on the advance payment amounts calculated in accordance with § 155.1030(b)(3) of this subchapter”).
In 2017, after the latest presidential election and the failed attempts to repeal and replace the ACA, HHS released a memo to health insurance issuers, supported by a legal opinion from then-Attorney General Jeff Sessions, which stated CSR payments to issuers would cease immediately.\(^{50}\)

**Status:** The U.S. District Court for D.C. found that Congress had not sufficiently appropriated funds for CSRs.

HHS reached a settlement with Minnesota and New York over the financial impacts to their Basic Health Programs.


**Summary:** There have been three types of lawsuits regarding CSRs: (1) Whether CSRs were properly appropriated by Congress; (2) the impacts of CSR nonpayment on Basic Health Programs;\(^{51}\) and (3) Payment of CSRs to qualified health plan issuers.

**Implications:** These three types of cases show that careful legislative drafting is important, but also that administrative changes in interpretation will almost certainly lead to protracted litigation.

1. **Whether CSRs were Properly Appropriated by Congress**

   Federal litigation over CSR payments began in November 2014, when the U.S. House of Representatives sued HHS, arguing that CSR payments to insurers were improper because there was no specific congressional appropriation to make them. In 2016, Judge Rosemary Collyer agreed that CSR payments to issuers was enjoined until a valid appropriation was made, but she stayed the injunction pending appeal.\(^{52}\) *House v. Burwell* (which would ultimately be changed to *House v. Azar*) was appealed to the U.S. Court of Appeals for the D.C. Circuit by HHS. In the meantime, President Trump was elected, and the Trump administration ended CSR payments to

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\(^{50}\) Letter from Eric Hargan, Acting Secretary, to Seema Verma, Administration of Ctrs. For Medicare & Medicaid Servs. (Oct. 12, 2017), available at https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf (“In light of that opinion – and the absence of any other appropriation that could be used to fund CSR payments – CSR payments to issuers must stop, effective immediately. CSR payments are prohibited unless and until a valid appropriation exists.”).

\(^{51}\) Basic Health Programs are governed by ACA Section 1331 as a health benefits coverage program for low-income residents who are not eligible for Medicaid and would otherwise be enrolled in qualified health plans. Basic Health Program, Medicaid.Gov (last visited May 21, 2019), https://www.medicaid.gov/basic-health-program/index.html. A Basic Health Program is funding through a 95% match of the premium tax credits and cost-sharing reductions that would have otherwise been provided to eligible individuals if they had enrolled in qualified health plans. *Id.*

issuers in October 2017. The parties to the litigation subsequently agreed that there was no need to resolve the lawsuit.

State attorneys general then filed a separate lawsuit, California v. Trump, against HHS for ending CSR payments to QHP issuers. The plaintiff states sought declaratory and injunctive relief to “compel President Trump and the federal agencies to make CSR reimbursement payments in accordance with the ACA and its permanent appropriation.” In July 2018, Judge Vince Chhabria of the U.S. District Court for the Northern District of California dismissed the case without prejudice.

2. The Impacts of CSR Nonpayment on Basic Health Programs

Minnesota and New York are the only states with approved Basic Health Program blueprints. On January 26, 2018, Minnesota and New York filed a lawsuit to challenge HHS’ “abrupt and unlawful cutoff of more than $1 billion annually in federal funding owed to the States to operate ‘Basic Health Programs’ (‘BHPs’).” In particular, the plaintiff states pointed to e-mails from HHS informing them that the agency would not be paying the $266 million due to New York and $32 million due to Minnesota for their BHP expenses in the first quarter of 2018—amounts that HHS described as the “CSR component” of the BHP payment. HHS’s sole justification for reducing its BHP payments, as articulated in these emails, was the federal government’s earlier decision in October 2017 to stop making CSR payments to insurers offering QHPs on exchanges.

On May 3, 2018, Judge Richard Sullivan approved a settlement between the parties, and HHS released its revised BHP funding methodology, providing an additional $422 million to New York and $46 million to Minnesota for their Basic Health Programs.

53 See supra note 48 (“In light of that opinion – and the absence of any other appropriation that could be used to fund CSR payments – CSR payments to issuers must stop, effective immediately. CSR payments are prohibited unless and until a valid appropriation exists.”).
60 Id. at 3.
3. Payment of CSRs to Qualified Health Plan Issuers

In six of the twelve cases filed, including one class action (Common Ground HealthCare Cooperative v. U.S.), the Court of Federal Claims granted the plaintiff insurers’ motions for summary judgment. The plaintiff insurers in these cases are seeking recovery of the cost-sharing reduction payments owed to issuers of qualified health plans in the individual market after the Federal Government ceased payments in October 2017. The Federal Government has appealed three of those cases (Montana Health Co-Op v. U.S., Sanford Health Plan v. U.S., and Community Health Choice v. U.S.) to the Federal Circuit. Montana Health Co-Op and Sanford Health Plan have been consolidated into one case, and the Federal Government filed its opening brief on March 22, 2019.

III. Regulatory Reforms

On October 12, 2017, President Trump released Executive Order 13813, entitled “Promoting Healthcare Choice and Competition Across the United States.” Within the Executive Order, President Trump directed the Departments of Health and Human Services, Labor, and Treasury to engage in rulemaking to expand access to association health plans, expand availability of short-term, limited-duration insurance policies, and expand the availability and permitted use of health reimbursement arrangements.

A. New York v. U.S. Department of Labor

Status: The U.S. Department of Labor has appealed the District Court’s ruling to the Court of Appeals for the District of Columbia on April 26, 2019. As of May 21, 2019, the U.S. Department of Labor has not requested a stay of the District Court’s decision, but has issued several pieces of subregulatory guidance on how existing association health plans under the new regulations should operate in light of the District Court’s decision. Final briefs on the appeal are due August 8, 2019.

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63 For a comprehensive list of the various CSR lawsuits, see Cost Sharing Reductions Payments, AFFORDABLE CARE ACT LITIGATION (last visited May 21, 2019), https://affordablecareactlitigation.com/cost-sharing-reductions-payments/.
64 See supra note 48.
67 Id.
**Summary:** Because of Executive Order 13813, the U.S. Department of Labor engaged in rulemaking interpreting ERISA Section 3(5) to broaden the interpretation of “employer” under ERISA, with the stated goal of allowing small employers, and working owners, to band together to purchase health insurance coverage that is available to large employers.\(^{71}\) The U.S. Department of Labor finalized its rule on June 21, 2018.\(^{72}\)

New York and twelve other states filed a complaint on July 26, 2018 in the U.S. District Court of DC, alleging that the final rule conflicts with the statutory structure of ERISA and the ACA.\(^{73}\) The plaintiffs sought a declaratory judgment that the final rule is invalid and requested the Court vacate the rule in its entirety.\(^{74}\) The District Court agreed, finding that the inclusion of working owners into the definition of “employer” contradicted the statutory language of ERISA, and the final rule’s interpretation of “commonality of interest” to include geography was also an unreasonable interpretation of ERISA.\(^{75}\) The District Court vacated the rule and remanded it back to DOL to consider how the final rule’s severability provision affects the remaining portions of the rule.\(^{76}\)

**Implications:** Several association health plans formed under the final rule’s new option for association health plans, so vacating the rule impacts enrollees under those plans. DOL’s appeal was expected, but what is unclear is whether DOL will seek a stay of the District Court’s ruling, and what happens at the end of the plan year when the DOL and HHS non-enforcement period expires.

**B. Association of Community Affiliated Plans v. U.S. Department of Treasury**

**Status:** Parties finished briefing on the plaintiffs’ motion (and defendants’ cross-motion) for summary judgment on March 22, 2019. A hearing on the summary judgment motions is scheduled for May 21, 2019.\(^{77}\)

**Summary:** In response to Executive Order 13813, the U.S. Departments of Health and Human Services, Labor, and Treasury jointly engaged in rulemaking to expand the definition of short-term, limited-duration insurance policies. Under the Obama Administration, the agencies limited short-term, limited-duration insurance policies to those offered for less than three months. On

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\(^{72}\) Definition of “Employer” Under Section 3(5) of ERISA – Association Health Plans; Final Rule, 83 Fed. Reg. 28912 (Jun. 21, 2018) The rule permits “Track 1” association health plans, which may operate under the DOLs’ pre-2018 guidance, and “Track 2” associations, which may operate under the new regulations at 29 CFR 2510.3(5).

\(^{73}\) State of New York v. U.S. Department of Labor focuses on the “Track 2” association health plans.

\(^{74}\) Id. at 8.

\(^{75}\) Id. at 141.

August 3, 2018, the agencies finalized the definition of short-term, limited duration insurance policies to mean

health coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total.78

The Association for Community Affiliated Plans and six other organizations filed a complaint on September 14, 2018, in the U.S. District Court for the District of Columbia.79 The plaintiffs allege that the final rule should be set aside as arbitrary and capricious and contrary to law.80 The defendants filed a motion for summary judgment, arguing that plaintiffs do not have standing.81

The plaintiffs originally filed a motion for a preliminary injunction, but withdrew the motion on November 7, 2018.82 In February of 2019, the plaintiffs filed a motion for summary judgment,83 and the defendants filed a cross-motion for summary judgment.84 Within its motion for summary judgment, the defendants assert that the plaintiffs do not have standing. Additionally, the defendants argue that the final short-term, limited-duration policy final rule is consistent with Congress’ legislative judgments,85 statutory language, and is not arbitrary and capricious.86

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80 Id. at 14.
85 "The STLDI Rule simply exercises the Departments’ express delegation of authority to define an ambiguous and undefined statutory phrase consistent with how it had long been defined both before the ACA and when Congress enacted that ACA.” Reply in Further Support of Defendants’ Motion for Summary Judgment at 15, Ass’n for Cmty. Affiliated Plans, et al. v. U.S. Dep’t of Treasury, et al., No. 18-2133, Document 46 (Mar. 22, 2019), available at https://affordablecareactlitigation.files.wordpress.com/2019/03/5931940-0-10459.pdf
86 “The Departments also fully explained their decision to allow renewals of up to 36 months, as the Departments have shown. Defs.’ Mot. at 40-42; Defs.’ Opp’n at 28. Plaintiffs’ argument that this explanation was unreasonable simply asks the Court to substitute its judgment for the considered judgment of the Departments.” Id. at 21.
Implications: The final rule, with its change in the definition of short-term, limited-duration insurance policies, was effective October 2, 2018, so a decision to vacate the rule would impact individuals currently enrolled in short-term, limited duration insurance policies.

IV. Take Care Clause

Status: A response to the Government’s motion to dismiss the amended complaint are due May 31, 2019.

Summary: In August of 2018, the cities of Columbus, Baltimore, Cincinnati, Chicago, and two individual plaintiffs, filed a complaint against President Trump in the U.S. District Court of Maryland, seeking declaratory and injunctive relief. The plaintiffs allege that the Trump Administration’s actions to “sabotage and, ultimately, to nullify the [ACA]” violate the Take Care Clause of the U.S. Constitution and the Administrative Procedures Act. The complaint cites various actions taken by the Trump Administration, including:

- Promoting insurance that does not comply with the ACA’s requirements, including insurance that does not cover preexisting conditions;
- Slashing funding for outreach strategies that have been proven to encourage individuals, and healthy individuals in particular, to sign up for coverage;
- Misusing federal funds for advertising campaigns aimed at smearing the ACA and its exchanges, and spinning false narratives about the efficacy and success of the Act;
- Providing individuals and families with less time to choose a plan that is appropriate for them; and
- Imposing unnecessary and onerous documentation requirements, making enrollment even harder.

The defendants filed a motion to dismiss in late 2018, and plaintiffs filed an amended complaint on January 25, 2019. The plaintiffs allege that many of the provisions in the Final 2019 Notice of Benefit and Payment Parameters are arbitrary and capricious under the Administrative Procedures Act. The plaintiffs also claim that the Trump Administration has violated that Take

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87 Id.
91 Complaint for Declaratory and Injunctive Relief at 124, City of Columbus, et al., v. Donald Trump, et al., Case No. 18-cv-2364, Document 1 (Aug. 2, 2018), available at
Care Clause of the U.S. Constitution by “failing to take care to faithfully execute the Affordable Care Act.”

Regarding the second claim, in a second brief supporting the motion to dismiss, the Administration argues that separation of powers principles bar a court from issuing declaratory or injunctive relief against the President, the Take Care Clause is not a proper vehicle for challenging the President’s discretionary, political acts, and that the discretionary actions of the federal agencies cannot give rise to a claim under the Take Care Clause.

Implications: The Take Care Clause has historically played a limited role in constitutional litigation, so this will be an interesting case to watch if it proceeds.


92 Id. at 126.
93 Defendants’ Motion to Dismiss Plaintiffs’ Amended Complaint, City of Columbus, et al., v. Donald Trump, et al., Case No. 18-cv-2364, Document 52 (Mar. 8, 2019), available at https://affordablecareactlitigation.files.wordpress.com/2019/03/columbus-us-mo-dism.pdf.
Healthcare Fraud and Abuse Update
2018-19: Notable Cases, Developments and Trends

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Healthcare Fraud & Abuse Update
2018-19: Notable Cases, Developments, and Trends
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Agenda

• False Claims Act Trending Topics
  – Recent statistics
  – Implied certification / materiality litigation post-Escobar
  – Medical necessity issues
  – New targets and theories

• Other Fraud and Abuse Developments

• Department of Justice Policy Statements
  – Impact of the Granston Memo

• Other Recent Cases
A little hospital lawyer humor...

“Has your address, insurance, or family relationship changed since you started filling out these forms?”

Healthcare FCA Statistics
Enforcement Trends

Number of filed HHS FCA cases

Enforcement Trends

HHS FCA Recoveries

Healthcare Recoveries ($M)
Under Escobar, the implied certification theory requires:

1. an affirmative specific representation about the goods or services provided, and
2. proof of noncompliance with a material statutory, regulatory, or contractual requirement.

Specific representation requirement adopted by some courts:

- Fourth and D.C. Circuits – specific representations (“misleading half-truths”) alone could establish implied certification liability
- First, Seventh, and Ninth Circuits – specific representations and noncompliance with material requirement are both necessary to establish liability

Noncompliance with the requirement must be material to the Government’s payment decision

- Relator or Government must also show that the defendant knew that the requirement was material
- Materiality requirement is “demanding” and must be pleaded with particularity in an FCA complaint
Implied Certification / Materiality Litigation Post-Escobar

- Every complaint relying on an implied certification theory should be evaluated as follows:
  - Does the complaint allege there was an affirmative specific representation about the goods or services provided on the claim?
  - Does the complaint allege how the alleged violation was material to the payment decision of the relevant payor (in more than an conclusory fashion)?
    - Are there objective facts alleged that undermine this assertion, such as continued payment by the government payor?
  - Does the complaint allege that the defendant knew the violation was material?
- If complaint does not sufficiently allege materiality, a motion to dismiss may be appropriate.
- If it does sufficiently allege them (or the motion to dismiss is unsuccessful), these matters should be a focus in discovery.

Implied Certification / Materiality Litigation Post-Escobar

- A January 2018 district court decision vacated a jury’s verdict totaling nearly $350M in FCA damages and penalties
  - United States ex rel. Ruckh v. Salus Rehabilitation (M.D. Fl.)
  - Court held relator failed to prove allegations that a nursing home’s failure to maintain care plans allegedly required by Medicare regulations was material to the government’s payment decision.
  - The court found “that the federal and state government regard the disputed practices with leniency or tolerance or indifference or perhaps with resignation to the colossal difficulty of precise, pervasive, ponderous, and permanent record-keeping in the pertinent clinical environment.”
- Most courts agree with Ruckh – if the government continues payment to a contractor after becoming aware of allegations of the contractor’s non-compliance, it cannot prove the noncompliance was material.
Key FCA Developments

Gilead Sciences Inc. v. United States ex rel. Campie

- Cert. Petition denied – January 2019
- Background
  - Defendant marketed three drugs for use in HIV treatment; relator alleged manufacturing issues; FDA monitored production and sent letters warning of potential regulatory violations
  - FDA didn’t rescind approval of medicines; DOJ did not intervene in relator’s suit
  - 9th Circuit did not find payment despite government knowledge of the defendant’s violations to necessarily establish that violations were material. Could be lots of reasons government would continue to pay despite allegations.
  - Dispute is over how government knowledge of mere allegations of misconduct affects materiality analysis
    - The Supreme Court in Escobar stated that continued payment that “actual knowledge that certain requirements were violated” is strong evidence that a violation is not material, but the solicitor general (SG) endorsed a “holistic inquiry.”
    - SG argued that continued payment by itself did not warrant dismissal. In its brief, the SG stated that “an FCA relator cannot rest solely on ‘conjecture or ‘speculation’” and also acknowledged that not all violations are material violations.
    - After Supreme Court denied cert., Justice Department dismissed the case, citing high discovery burden, supporting notion government did not find the alleged falsity to be material in this case.
Does DOJ’s intervention decision bear on materiality?

- How the government reacts when presented with allegations in a sealed qui tam complaint is being considered in judicial determinations of materiality
- In *United States ex rel. Folliard v. Comstor Corporation* and *United States ex rel. Cressman v. Solid Waste Services* courts found it relevant that government declined after investigating
  - Courts expressly considered the government’s decision not to intervene in ruling that the violations alleged by relators was not material
  - Ignored boilerplate disclaimers by DOJ that declination decision was not merit-based
- If government’s decision to intervene becomes a referendum on the whether the alleged falsity was material to the government’s decision to pay:
  - DOJ may feel compelled to intervene more often
  - There may be more depth to pre-decisional investigations by DOJ

Proof requirements related to AKS cases

- FCA may serve as a private cause of action for violations of other statues. The Anti-Kickback Statute, for example, is often a legal hook for FCA cases even though it provides other governmental remedies. In this way, AKS violations render claims “legally false” for purpose of FCA, because the claim is “tainted.” However, courts are increasing proof requirements for plaintiffs in these “tainted” claim actions.
- The 3rd Circuit in *Greenfield v. Medco Health Solutions* rejected the argument that the “taint” of alleged kickbacks automatically “renders every reimbursement claim false.”
  - Rather, on summary judgment, a plaintiff needs to demonstrate “at least one claim that covered a patient who was recommended or referred” in violation of the AKS
  - The kickback scheme must be linked to a particular claim, otherwise the FCA defendant is entitled to summary judgement
- In the 11th Circuit, *Carrel v. AIDS Healthcare Foundation* required particular allegations about actual submissions of false claims at the motion to dismiss stage.
  - Relators participated in financial review meetings and in the provision of health care services
  - The court found they only alleged “background factors” that did not rise to an actual false claim
  - Relators were not permitted to “rely on mathematical probability to conclude that [Defendant] surely must have submitted a false claim at some point”
Granston Memo

What deference is owed when DOJ moves to dismiss a declined case?

- 32 U.S.C. § 3730(c)(2)(A)
  - The government may dismiss an action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for hearing on the motion.
  - Historically invoked when claims were jurisdictionally barred (public disclosure, original source, first-to-file)
  - Expanded to curb meritless claims and manage government resources
  - In 2018, DOJ filed 16 motions to dismiss under 3730(c)(2)(a) (10 connected with National Healthcare Analysis Group)

- Growing split between D.C. Circuit (Swift) and Ninth Circuit (Sequoia Orange) approaches
  - Ninth Circuit requires government to articulate a “valid government purpose” served by dismissal
  - In United States v. Academy Mortgage Corp., the court held that relators were entitled to an evidentiary hearing because “the Government ha[does] not fully investigated the allegations.” DOJ called ruling “improper and unprecedented”
  - In U.S. ex rel. Maldonado v. Ball Holmes LLC, the court held that the government has “unfettered” discretion to dismiss qui tam complaints. This followed the approach taken by the D.C. Circuit in Swift.
  - NHCA cases – Illinois court ruled that dismissal was not appropriate and may have been informed by animus toward relator

- Defendants often have to persuade DOJ to dismiss a declined case
  - The 9th Circuit approach dis-incentivizes DOJ from filing such motions because they must meet a higher burden

Medical Judgment
Continued Scrutiny Regarding Medical Judgments

• Courts are divided regarding whether professional judgment can be “false”, but more recent cases favor the government

  – *U.S. v. Paulus*, 894 F.3d 267 (6th Cir. 2018) – Cardiologist convicted for inflating extent of artery blockage; district court granted motion for acquittal; Sixth Circuit reversed because degree of blockage “is a fact capable of proof or disproof”.

  – *U.S. ex rel. Polukoff v. St. Mark’s Hospital*, 895 F.3d 730 (10th Cir. 2018) – Relator alleged Dr. Sherman Sorensen performed “thousands” of unnecessary heart surgeries (patent foramen ovale closures) and certified procedures were necessary to prevent recurrent stroke, because Medicare would not pay for other bases. Court allowed profit motive to permit inference of fraudulent intent.

  – *United States ex rel. Paradies v. AseraCare, Inc.*, 176 F. Supp.3d 1282 (N.D. Ala. 2016) (11th Circuit decision pending) – alleged false certifications that hospice patients had life expectancy of six months or less. Lower court said expert disagreement isn’t enough to establish false claims absent “additional objective evidence”

  – *United States ex rel. Ribik v. HCR ManorCare, Inc.*, No. 1:09-cv-00013 (E.D. Va. Nov. 17, 2017) - DOJ voluntarily dismissed a long-running FCA case following the magistrate judge striking the government’s expert report and excluding the witness because she lacked the necessary expertise.

New Targets and Theories
New Targets and Theories: Opioids

• **August 2017: DOJ Opioid Unit announcement**
  – Using data analytics to identify prescriber targets
  – 12 dedicated AUSA

• **February 2018: AG Sessions announcement of PIL Task Force**
  – Interagency cooperation (including FDA and DEA)
  – Wide array of enforcement tools, including the FCA, to combat opioid epidemic
  – Involvement in Ohio MDL re prescription opioid litigation
  – Follow-up statements by Deputy AGs reinforce focus

• **June 2018: DOJ/HHS Takedown**
  – Largest healthcare fraud enforcement action in DOJ history, including 162 defendants, 76 of which were doctors.

• **August 2018: First CSA civil injunctions**
  – DOJ issued the first-ever civil injunctions under the Controlled Substances Act against doctors who allegedly prescribed opioids illegally.

• **October 2018: $329 million award**
  – DOJ announced an award of almost $320 million to a variety of entities and programs, including drug courts, research efforts, and programs aimed helping impacted children and youth, in an effort to combat the opioid crisis in America.

• **April 2019: Appalachian Regional Prescription Opioid Strike Force**
  – FBI and DOJ announced criminal charges against 60 defendants—including 53 doctors, pharmacists, nurse practitioners, and other medical professionals who allegedly gave thousands of opioid prescriptions to addicted patients, essentially acting as their patients’ drug dealers.

• **June 2019: 24,000 cities and counties in MDL make proposal for comprehensive settlement**
New Targets and Theories: Opioids

DOJ Settlement with Opioid Manufacturer Insy

• Five former executives convicted in May 2019 in RICO bribery scheme
• As part of global settlement of False Claims Act and illegal promotion charges, Insy agreed to pay $225 million ($195m civil; $30m criminal fine)
• Corporate Integrity Agreement (CIA) with unprecedented enforcement and breach provisions, including:
  – OIG’s release of permissive exclusion authority contingent on Insy satisfactorily complying with the CIA
  – Insy must divest Subsys and a buprenorphine candidate product; it must cease all business related to opioids within 12 months and cease marketing the product within 90 days
  – No incentive compensation for sales that may include off-label promotion
  – Insy is prohibited from making payments to non-employees
• Days after Insy agreed to the settlement it filed for bankruptcy

New Targets and Theories: Opioids

Indivior Indictment

• Suboxone Film: partial opioid agonist (buprenorphine) with naloxone used for medically assisted treatment of OUD
• Indivior Inc. indicted by a federal grand jury for allegedly:
  – Misleading health care providers into believing Suboxone Film was safer, less divertible, and less prone to abuse than similar drugs
  – Connecting opioid users to doctors prescribing opioids at high rates and in a clinically unwarranted manner
  – Causing state Medicaid programs to expand and maintain coverage of the drug at a substantial cost to the government
New Targets and Theories: Opioids

- **Expect to see:**
  - Criminal convictions of physicians and pharmacists
  - Civil FCA cases involving physicians, treatment centers, labs, pharmacies
  - OIG CMP and exclusion cases with physicians
  - More OIG Workplan items addressing providers and CMS oversight
  - Part D sponsors imposing over-prescribing safeguards
  - State prosecutions and state laws imposing prescribing restrictions

New Targets and Theories: Patient Assistance Programs

- OIG rescission of Advisory Opinion 06-04 in November 2017
  - Believed PAP Caring Voice Coalition was providing patient-specific information that would enable the manufacturer to correlate donations with sales
  - Caring Voice Coalition shut down all disease funds
  - Challenged OIG action as alleged violation of First Amendment rights
- Active investigation in Boston of a large number of pharma manufacturers’ contributions to charitable organizations that assist patients with copays
  - April 2019 - Astellas - $100m; Amgen - $25m; Jazz - $57m; Lundbeck - $52m; Alexion - $13m (no CIA)
  - Earlier settlements:
    - Actelion $360 million
    - United Therapeutics $210 million settlement
    - Aegerion $36 million settlement
    - Pfizer $24 million settlement
New Targets and Theories: Pain Compounding Products

• June 2019 – Three doctors and five marketers indicted for alleged kickback scheme involving compounded products
  – Pharmacies in Oklahoma and Texas allegedly paid kickbacks to physicians to refer compounded pain medication prescriptions to their pharmacies using pre-printed prescription pads
  – Doctors allegedly served as medical directors or study investigators to disguise payments
  – Marketing companies coordinated the arrangement
• There are a large number of these cases under investigation

New Targets and Theories: Home Health

Home Health

• Vulnerable – History of Fraud/Abuse
  – Medical Necessity
  – Kickbacks
  – Compliance audits

• OIG Multi-Disciplinary Approach

• OCIG Industry Outreach
New Targets and Theories: Home Health

Home Health

- OIG seeks to reduce fraud, waste, and abuse and enhance program integrity in home and community settings through outreach, education, audits, evaluations, investigations, and administrative enforcement that reduce Medicare spending to home health providers in geographic “hot spots”

Vulnerabilities in Hospice Care

Over the past decade, hospice use has grown steadily. Medicare paid $16.7 billion for hospice care in 2016.

Since 2006:

- 81% Increase in spending for hospice care
- 43% Increase in the number of hospices
- 53% Increase in the number of hospice beneficiaries

Source: Vulnerabilities in the Medicare Hospice Program: Effect on Quality Caring and Preventing Fraud - Earnings MORE: https://www.hhs.gov/opi/hsp/penit/index.html
**New Targets and Theories: Home Health**

**Medicare Hospice**

- OIG Portfolio (July 2018)
- OIG and CMS leadership engaged on recommendations

**Ongoing work on quality and safety**
- Trends in hospice deficiencies and complaints (early Summer)
- Protecting hospice patients from harm (early Summer)
- Timeliness of complaint investigations (late Fall)

**Other Recent Developments**

- **Billing for unnecessary equipment**
  - **Rotech** (April 2018 settlement) - Supplier of portable oxygen paid **$9.68 million** to settle allegations that it knowingly billed Medicare for portable oxygen supplies for patients who did not need them
  - The company automatically billed for portable oxygen supplies without verifying that patients used or needed portable oxygen and without verifying delivery
- **Routinely waiving co-pays and deductibles to win business**
  - **Lincare** (August 2018 settlement) - Supplier of oxygen paid **$5.25 million** to settle allegations that it routinely waived co-pays and deductibles for members of a Medicare Advantage plan that had signed an exclusive network deal with a competing supplier
  - The company allegedly violated the Anti-Kickback Statute and False Claims Act by inducing patients to choose Lincare’s products over the competitor’s products, then submitting claims for those products at much greater expense to the government
Other Recent Developments

• Lavish meals for potential customers
  – **Abiomed** (March 2018 settlement) – Manufacturer of heart pumps paid **$3.1 million** to settle allegations that its employees bought extremely expensive meals for physician customers and their guests
  – Rare case based solely on allegations of lavish meals
    – Settlement named “some of the country’s most expensive restaurants” with costs far exceeding the company’s own guidelines
    – Excessive amounts of alcohol
    – Spouses of physicians invited to attend
    – Employees falsified number of attendees to make the true per-person cost look lower
  – Cases involving **Teva** and **Novartis** are scheduled for trial

Other Recent Developments

• Sham device registry
  – **Covidien** (December 2018) - $13 million civil settlement to resolve allegations that the company paid kickbacks to hospitals in the form of sham fees for submitting clinical data about the company’s device; company knowingly used the fees to convert customers from other devices and increase sales

• FDA promotional violations
  – **AngioDynamics** (July 2018) - $12.5 million settlement - company allegedly marketed an unapproved device with false and misleading promotional claims
  – **Ev3** (December 2018) - $17.9 million plea agreement - company pled guilty to encouraging use of its device outside limited approved use in brain; sales reps instructed physicians how to use off-label and sales quotas/bonuses were tied to unapproved uses
Other Recent Enforcement – Debt Forgiveness

**Roche Diagnostics Corp.**

- Roche and Humana facing FCA suit alleging that Roche regained formulary status for its diabetes products with Humana by forgiving large debt that Humana had incurred
  - Relator alleges that, after Humana dropped Roche’s drugs from its formulary, she discovered that Roche had paid Humana $45 million in rebates it was not required to pay
  - Roche and Humana allegedly negotiated a deal in which Roche was returned to the formulary and Humana paid $11 million to settle the debt
- DOJ declined to intervene in May 2017, but court denied motion to dismiss in June 2018. Recent ruling on procedural issue.

Other Recent Enforcement

**Travel Act**

- Forest Park Medical Center – Physician-owned surgical hospital established in 2009
  - DOJ indicted 21 FPMC founders and investors, executives, and physicians
    - Alleged that defendants 1) refused to join insurance plan networks in order to maximize reimbursement; 2) paid kickbacks to physicians in exchange for referrals; and 3) laundered proceeds through sham business ventures
    - 10 defendants pled guilty
  - In April 2019, jury convicted 7 other defendants
    - Managing partner faces up to 65 years; 3 spinal surgeons were convicted for conspiracy, kickbacks, and money laundering; nurse who recruited and preauthorized worker’s comp claims faces 10 years
- Rarely used but very powerful enforcement tool
Other Recent Enforcement

Travel Act

- Penalties
  - 5 year max for non-violent offenses
  - Fine = maximum of either $250,000 or twice gross gain/loss
- Different than healthcare fraud/kickback offenses
  - No requirement of “fraud”; no need to prove material false statement
  - No federal health care benefit program involvement
- Predicate for 18 USC 371 Conspiracy (Conspiracy to Violate the Travel Act)
  - Based on violation of state law, but no double jeopardy in case of separate state prosecution
  - Elements of Predicate State Offenses Vary Widely

Co-Marketing and the Covidien Case

- In March 2019, Covidien paid over $17 million to settle allegations it provided illegal remuneration in the form of practice and market development support to physicians
  - To induce the purchase of Covidien’s vein ablation products, the company is alleged to have provided support that included –
    - Customized marketing plans for specific vein practices
    - Scheduling and conducting “lunch and learn” meetings and dinners with other physicians to drive referrals to specific vein practices
    - Planning, promoting and conducting vein screening events to cultivate new patients for those practices

“Today’s settlement serves as an important reminder to those in the health care community that unlawful kickbacks come in many forms and are not limited to monetary payments to providers.”

Jody Hunt
Assistant Attorney General, DOJ
Other Fraud and Abuse Developments

Proposed Rule: Anti-Kickback Statute ("AKS")

February 8, 2019

• Trump administration has proposed a series of changes to the anti-kickback statute's (AKS) safe harbor rules that seek to eliminate the use of rebates in Medicare Part D and Medicaid managed care plans.

• Three new safe harbor provisions
  – Elimination of safe harbor protection for certain drug rebates
  – New safe harbor for point-of-sale discounts to patients
  – New safe harbor for PBM service fees

• Two big questions:
  – Will it actually lead to lower drug prices for federal plans and beneficiaries
  – Will the proposed rule’s elimination of PBM rebates carry over into the private insurance market?
Proposed Rule: AKS

Fraud and Abuse Laws as a Barrier to Value-Based Arrangements

• AKS was designed to apply to sales of items and services reimbursed on a cost or fee-for-service basis
  – Key safe harbors are almost 30 years old
  – AKS discount safe harbor is designed to protect discounts and rebates – “mere reduction in price”
  – Government has resisted application of safe harbor to bundled product/service offerings aimed as reducing adverse events and associated costs
  – Other safe harbor concepts like “fair market value” and compensation “set in advance” are obstacles to meaningful risk-sharing
  – Successful VBAs often require planning and support services that risk being cast as unlawful free services
    – e.g., information technology, systems design, “Lean Sigma,” care protocols, data analytics, supply chain optimization, adherence monitoring
• The explosion of FCA litigation in the intervening years creates real-world risk

Proposed Rule: AKS

Is Help Finally on the Way?

• Cassidy-Warner Bill
  – Would create a statutory exception the AKS for VBAs
• OIG Request for Information (August 2018)
  – Notes that HHS is working to transform the health care system into one that pays for value, and solicits input for removing unnecessary regulatory obstacles
  – AdvaMed proposed the creation of 3 new safe harbors for (1) value-based pricing, (2) value-based warranties, and (3) risk-sharing arrangements
    – Together, they would allow for a variety of pricing terms and adjustments (e.g., rebates, withholds), payments (e.g., shared savings payments, underachievement payments) and replacement products and services when tied to the achievement of measurable clinical or cost outcomes
    – Also would protect planning and support reasonably necessary or appropriate to achieving the purposes of the arrangement, such as analysis, software, equipment, information and/or services
• Proposed Regulation Pending at OMB – Scheduled Release July 2019
Notable Items in the New AdvaMed Code

Effective January 1, 2020

• 2 new sections on—
  – Communicating for the Safe and Effective Use of Medical Technology
    – i.e., principles for communicating on unapproved uses – truthful & non-misleading; information provided by authorized personnel; identify information as off-label when communicating; develop controls and polices
  – Principles for Company Representatives Providing Technical Support in the Clinical Setting
    – i.e., direction/supervision of HCP; company personnel should be transparent that they are acting on behalf of company; cannot interfere with HCP decision-making; patient privacy; credentialing; cannot eliminate overhead expense
• Distinguishes commercial sponsorships (e.g., exhibit space, advertising) from grants and donations
  – Sponsor benefits (e.g., additional badges, golf event) cannot be passed on to HCPs
• Adds language to permit companies to host a "Satellite Symposium"
  – Company organized, funded and controlled, but on the agenda of a third-party meeting/conference
  – Company may pay registration fees and travel costs for faculty, but not for attendees
• Clarifies that travel is not permitted for general education events
• Adds language on consignment products and recommendations for controls (e.g., periodic inventories)

Notable Items in New AdvaMed Code

Jointly Conducted Education and Marketing Programs

• The Code suggests the following principles –
  – There must be a bona fide, legitimate need for the company to engage in the activity for its own benefit
  – Participating HCPs should be required to comply with company guidelines on off label promotion and appropriate health economics information
  – Programs should be balanced and promote both the company’s technologies and the HCP
  – Company and HCP “should serve as bona fide partners in the program and should make equitable contributions towards the activity and its costs”
    – e.g., developing content, invitations, space rental, AV needs and other event costs
  – The arrangement should be documented in a written agreement
New AdvaMed Code: Other updates

- Encourages companies to develop meal policies, including by establishing a per-meal spending limit which may take geographic differences into account
- Provides principles on selecting appropriate venues, which should be centrally located, easily accessible, conducive to the exchange of information, and should not be selected for luxury or entertainment
- Clarifies circumstances in which Companies may not pay for travel
- Expands guidance on evaluation and demonstration products to include consignment products for use in HCP clinical settings
- New guidance on satellite symposia

DOJ Policy Statements
DOJ Policy Statements

• Issued on April 30, 2019, “Evaluation of Corporate Compliance Programs”
• Three fundamental questions a prosecutor should ask:

  1. **“Is the corporation’s compliance program well designed?”**
     - Directs prosecutors to examine the “comprehensiveness of the compliance program” for clear messaging regarding a company’s intolerance of misconduct and thorough integration of compliance policies and procedures into ongoing corporate operations.

  2. **“Is the program being applied earnestly and in good faith?”** In other words, is the program being implemented effectively?
     - Whether a compliance program has been put in place “in an effective manner,” with adequate resources devoted to ensuring that staff will “audit, document, analyze, and utilize the results of the corporation’s compliance efforts”
     - Whether employees are adequately informed of the program

  3. **“Does the corporation’s compliance program work” in practice?** Prosecutors may consider:
     - Evidence of a company’s “continuous improvement, periodic testing, and review” of compliance systems
     - The existence of a “well-functioning and appropriately funded mechanism” for timely investigating alleged misconduct, and
     - The extent to which a company is able to conduct a “root cause analysis” of any identified misconduct, accompanied by appropriate remediation measures.

Updated DOJ Guidance: Effective Corporate Compliance Programs
Updated DOJ Guidance: FCA Cooperation

• DOJ policy issued May 7, 2019 as DOJ Manual guidance
• Governs when cooperation credit should be given to the targets of False Claims Act investigations:
  – **Relatively vague.** The guidance notes that “discretion [to give cooperation credit] will be exercised by reducing the penalties or damages multiple sought by the Department,” without providing specifics on how that credit would be provided in practice.
  – **Company must still make restitution.** The policy states that the “maximum credit that a defendant may earn may not exceed an amount that would result in the government receiving less than full compensation for the losses caused by the defendant’s misconduct (including the government’s damages, lost interest, costs of investigation, and relator share).”
    – Language suggests that maximum credit would result in a settlement for no less than single damages, plus interest, investigation costs, and relator share.
    – In practice, such a sum would be analogous to a **damages multiplier of 1.5 or higher**

**Other Recent Cases**
Several aspects of the Parts C and D overpayment regulation were challenged in *UnitedHealthcare Insurance Co. v. Azar*, No. 16-157 (D.D.C.).

In September 2018, the court found the standard for when an overpayment is “identified” by an MA plan unlawful and vacated the rule:

- Inconsistent with the express wording of the FCA (as amended by the ACA)
- CMS definition for “identified” contemplates the exercise of “reasonable diligence” while the FCA imposes liability only when an individual or entity “knowingly” submits to the government a false claim for payment
  - “knowingly” is a term defined in the FCA to include false information about which a person:
    - “has actual knowledge”
    - “acts in deliberate ignorance of the truth or falsity of the information” or
    - “acts in reckless disregard of the truth or falsity of the information”

Including the “should have determined” standard in the definition of “identified” went beyond the FCA’s “knowingly” standard.

Requiring “proactive compliance activities conducted in good faith” and reasonable diligence essentially creates a negligence standard
- the FCA is not a negligence-based statute; rather, it is intent-based

Background:
- DOJ’s alleged in FCA suit that United knowingly retained overpayments for unsupported diagnosis codes submitted for Medicare Advantage patients. DOJ’s motion for partial summary judgment was denied.

The *Poehling* court relied on the D.C. District Court’s reasoning in *UHC v. Azar* to reject DOJ’s arguments under the FCA:

- DOJ asked the Court to resolve whether United was required by regulation or contract to delete invalid diagnosis codes submitted to CMS for risk adjusted payments that it knew were unsupported by its beneficiaries medical records.
- In part, United argued that requiring it to delete unsupported codes would contravene the “actuarial equivalence” and “same methodology” provisions of Section 1853 of the Medicare Act.
- The district court described *UHC v. Azar* as “persuasive authority.”
- In *Poehling*, as in *Azar*, the government’s argument would result in uneven reimbursement by CMS for Medicare advantage and traditional Medicare programs and therefore would violate the “Actuarial equivalence” and “same methodology” requirements of the Medicare Act.
Recent Supreme Court decision: *Azar v. Allina Health*

- **Holding:** Medicare interpretive guidance must go through notice-and-comment if it establishes or changes a substantive legal standard governing payment, coverage, or eligibility.

- **CMS will seek to narrow the impact of the ruling on the administration of Medicare program.**
  - Will likely argue that guidance documents are not substantive legal changes governing payment, coverage or eligibility, and therefore do not require notice-and-comment.
  - *Allina Health* court itself was skeptical that a significant number of manual provisions would need to be readopted through notice-and-comment rulemaking.

- **Potential for an expansive reading of* Allina Health***
  - CMS will be more likely to engage in notice-and-comment with respect to more controversial interpretations.
  - A broad understanding may inhibit CMS from issuing guidance where stakeholders would welcome direction.

- **Courts will be reluctant to construe the decision’s reasoning in a way that would practically impede the operation of the Medicare program.**

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**A final piece of health care humor...**

*Ask your doctor if taking a pill to solve all your problems is right for you.*
2019 Minnesota Legislative Session

Presented and materials prepared by:

PHIL GRIFFIN
Ewald Consulting
Saint Paul
# 2019 Minnesota Legislative Session

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When the final gavel sounded in the Chambers of the House and Senate on May 25th the legislature once again failed to meet its constitutional obligation to pass a balanced budget. The Governor and legislative leadership turned back to calling another Special Session. With a record 5,844 bills introduced during the session, the legislature set a modern day record for passing the fewest number of bills during a session by passing only 78 bills. While the quality of legislation should never be measured by the quantity of bills enacted into law, the lack of legislation led to another session of mammoth Omnibus bills being passed in the special session to enable the legislature to complete the real budget work required to run the state.

These bills were largely negotiated behind closed doors in the final days of session and during the days before the Special Session. The provisions were largely negotiated by the chairs of the major finance committees and then blessed by the “triumvirate” of the Governor, Majority Leader of the Senate and the Speaker of the House.

Of the 78 bills passed during the regular session 10 were health related and are summarized below. Several of these bills were substantial, including new laws to combat the opioid epidemic, regulate PBMs and regulate assistant living facilities The bulk of health care legislation was contained in the Omnibus Health and Human Services Finance Bill, SF 12. A summary of the major
Health Care Bills Passed in the Year One of the 91st Minnesota Legislature Regular Session

• **Chapter 3, H.F. 211** Adds licensed physical therapists to the list of health professionals who can provide a medical statement to obtain a disability parking permit or disability plates for physically disabled persons. Effective August 1, 2019.

• Chapter 7 [SF131](#) Requires a provider-based clinic to notify patients, before delivering nonemergency services, if it charges a facility fee and that such a fee may result in higher out-of-pocket expenses for patients. A facility fee is defined as a separate charge to a patient by a provider-
based clinic, in addition to a fee for services, that is intended to cover building, electronic medical records systems, billing, and other administrative and operational expenses. Effective August 1, 2019.

• Chapter 8 SF584 converts the allied health professionals regulated by the Board of Medical Practice (physician assistants, acupuncture practitioners, respiratory care practitioners, traditional midwives, registered naturopathic doctors and genetic counselors) to a licensure renewal cycle that is based on birth month. Effective August 1, 2019.

• Chapter 17 HF819 allows cardiovascular technologists who help with operating fluoroscopy equipment and who meet certain education, training, and supervision requirements, to assist with operating this equipment without passing an examination required for limited x-ray operators. Effective August 1, 2019.

• Chapter 22 SF1732 allows certain outpatient surgical centers to share facilities and allows for conditional licensure of these facilities for a limited time period. Effective August 1, 2019.
• Chapter 28  **SF955**  This law makes technical changes to health licensing and expand duty to warn and reciprocity for certain mental health professionals and social workers. Effective August 1, 2019.

• Chapter 31  **HF559**  This law requires providers to establish a provider-patient relationship through an examination, for the purposes of prescribing ophthalmic goods, and outlines requirements for the required examination. Effective August 1, 2019.

• Chapter 39 : **SF278**  Licenses and regulates pharmacy benefit management (PBMs). Effective August 1, 2019.

• Chapter 60,  **HF 90**  This law establishes assisted living resident consumer protections, prohibits deceptive marketing and business practices, establishes standards for independent senior living facilities and requires licensure, provides for penalties for violations, grants rule-making authority and requires reports. Various effective dates.

• Chapter 63  **HF400**, the omnibus opioids bill, this law requires drug makers and distributors to pay $20.9 million
in annual fees and allocates that money to combat opioid use disorders and fund the public safety response from county governments. Effective August 1, 2019.

Omnibus HHS Bill Passed in the Special Session

• **SF 12** (omnibus HHS bill)

  **Article 4: Continuing Care, beginning at page 170.14**
  Sections 1-8, 10-24 and 26
  Nursing facility property payment rate changes; requires all new nursing facilities to have their property rates determined under a new fair rental value property payment system; also requires facilities, upon completion of certain large construction or expansion projects, to have their property payment rates determined under a new fair rental value property payment system; establishes interim and settle-up payment rates for newly constructed or greatly expanded nursing facilities.

  **Article 6: Chemical and Mental Health, beginning at page 318.7**

  Sections 2 and 3, School-Linked Mental Health Grants
DHS is to establish a grant program to provide early identification and intervention for students and to build school capacity to support students. Lists who is eligible to apply for grants and how funds may be used.

Sections 6-39, 46-47 and 49
Updates to mental health statutes

Section 5
Chemical use assessments may be conducted via telemedicine

Section 52
MA covers Certified Community Behavioral Health Clinic services

Section 55
MA covers provider traveler time if a recipient requires the provision of mental health services outside of the provider’s usual place of business. Documentation is required.

Section 56 – PRTFs
The Commissioner may enroll an additional 80 PRTF beds beginning 7/1/20 and 70 additional PRTF beds beginning 7/1/23

Section 73
Law enforcement may share the names of inmates who have screened positive or may have a mental illness with local county social services agencies. The jail may refer an offender to county staff to arrange for services upon discharge and may share data.

Section 76
The Commissioner of DHS, in consultation with MCOs, counties, tribes and treatment stakeholders a plan and timeline to make system improvements to reduce paperwork for substance abuse disorder programs.

Section 78
The Commissioner of DHS, in collaboration with mental health providers and others, shall assess the school-linked mental health grant program and develop recommendations for improvement.
Article 7: Health Care, beginning page 383.5

Sections 3-4 and 26

Requires MA and MinnesotaCare to provide a step therapy override process

Section 8

Increases the application assistance bonus for navigators and agents who assist with enrollment in MA from $25 to $70

Sections 9-13

Makes payment adjustments for hospitals administering high cost drugs and in out-of-state hospitals in counties adjacent to Minnesota.

Sections 19 and 34

Requires an MA enrollee who is absent from the state for more than 30 days to be enrolled in FFS instead of PMAP. MCOs lose capitation.
Section 22

Allows local agencies to close MA case files if an enrollee’s renewal information is not submitted within 4 months.

Section 23

Community health workers may provide telemedicine services and lifts the cap on telemedicine services if the services are for the treatment of TB.

Sections 24-26 and 32

Modifies MA outpatient drug requirements and payments to conform to federal regulations.

Sections 30, 43-44

Creates an alternative payment method for FQHCs and rural health clinics and requires a study of FQHC and rural health clinic costs.

Section 37

Limits trend increases in MCO rates to an amount equal to a 0.8% reduction. There is a contingent backfill from the Minnesota Premium Security Account. This is
projected to save $29.5 million in 20-21 and $115.6 million in 22-23.

Section 45

Directs the Commissioner to develop and implement a corrective action plan to eliminate duplicate PINs and report back to the Legislature. This is projected to save $2.8 million in 20-21 and $4.9 million in 22-23.

Section 46

Establishes a Blue Ribbon Commission to identify ways to increase efficiency and find savings and better outcomes. The results are assumed to save $100 million in 22-23.

Article 8: Health Coverage, beginning page 446.24

Section 1

Provides for coverage of 3D mammograms
Sections 2, 18 and 21

Provides for health plans and MA coverage of treatments for PANDAS and PANS

Section 4-5, 9-11

Sets network adequacy requirements and a complaint process if these standards aren’t met; requires HMOs to put their provider networks on their website.

Sections 6-7, 19 and 22

Extends reinsurance through plan year 2021 and establishes payment parameters for benefit year 2020.

Section 8

Requires health plans to file with their rate information for prescription drugs.

Sections 12 and 14

Ensures mental health parity in health care coverage.

Sections 13 and 17
Prohibits the use of step therapy for metastatic cancer by health plans and MA.

Section 15
Imposes a limit on cost sharing requirements for insulin.

Section 20
Extends the moratorium on non-profit HMO conversion transactions, including transfers putting parameters around transfers.

Article 9: Prescription Drugs, beginning page 464.19

Sections 2, 5-6
Allows a pharmacy to dispense emergency refills of a script if certain conditions are met. Requires health plans to cover emergency refills as they would regular refills and makes other changes.

Sections 4 and 8
Requires health boards to inform licensees of the availability of obtaining information on obtain drugs at a lower cost that will be available on the Board of Pharmacy website. Requires the Board of Pharmacy to provide information on obtaining lower priced drugs on its website.

Section 7

Requires the Board of Pharmacy to establish a drug repository program by 1/1/20

Article 10: Health-Related Boards, beginning page 477.28

Sections 2-3

Modifies licensure requirements for graduates of foreign medical schools

Sections 24-48

Makes a number of Pharmacy Practice Act changes and increases licensure fees for drug manufacturers and wholesalers;

Sections 49-51
Requires the Board of Pharmacy to audit the electronic access to the PMP by permissible users. Allows patients who have been prescribed a controlled substance to access the PMP to determine who has obtained access to the patient’s data record.

**Article 11: Health Department, beginning page 529.24**

Section 2

Removes the mandate for interoperable electronic health records.

Section 17

Permits training grants for the primary care residency program to extend through the duration of the residency program.

Section 22

Requires the Commissioner to administer statewide tobacco cessation services.

Sections 23-31
Vaping devices are subject to the Clean Indoor Air Act, which means no vaping in health care facilities and clinics.

Section 32
Tweaks the public interest review process for hospitals seeking a bed moratorium exception.

Section 33
Increases the total number of allowed swing bed days at critical access hospitals.

Section 34
Requires a discharge plan to be in place before discharging certain adolescent patients.

Section 35
Requires hospitals to provide to discharged patients within 30 days an itemized description of billed charges.
PLENARY, THURSDAY, 9:30 a.m.

2019 HIPAA Privacy and Security Enforcement Update

Presented and materials prepared by:

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2019 HIPAA Privacy and Security Enforcement Update

Office for Civil Rights (OCR)
U.S. Department of Health and Human Services

2019 Health Law Institute
Minnesota Bar Association
June 20, 2019

Updates

• Breach Notification
• Enforcement
• Audit
BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY

Breach Notification Requirements

• Covered entity must notify affected individuals, HHS, and in some cases, the media
• Business associate must notify covered entity of a breach
• Notification to be provided without unreasonable delay (but no later than 60 calendar days) after discovery of breach
  — Annual reporting to HHS of smaller breaches (affecting less than 500 individuals) permitted
What Happens When HHS/OCR Receives a Breach Report

- OCR posts breaches affecting 500+ individuals on OCR website (after verification of report)
  - Public can search and sort posted breaches
  - Receive over 350 breach reports affecting 500 individuals or more per year
- OCR opens investigations into breaches affecting 500+ individuals, and into a number of smaller breaches
- Investigations involve looking at:
  - Underlying cause of the breach
  - Actions taken to respond to the breach (breach notification) and prevent future incidents
  - Entity’s compliance prior to breach

500+ Breaches by Type of Breach

- Sept 23, 2009 through April 30, 2019
  - Theft 33%
  - Unauthorized Access/ Disclosure 28%
  - Hacking/IT 25%
  - Improper Disposal 3%
  - Other 3%
  - Unknown 1%

- Jan 1, 2019 through April 30, 2019
  - Theft 3%
  - Loss 3%
  - Unauthorized Access/ Disclosure 23%
  - Hacking/IT 68%
  - Improper Disposal 3%
  - Other 3%
500+ Breaches by Location of Breach

Sept 23, 2009 through April 30, 2019

- Paper Records: 21%
- Email: 15%
- Network Server: 17%
- Laptop: 14%
- Desktop Computer: 11%
- Portable Electronic Device: 5%
- Other: 10%
- EMR: 6%

Jan 1, 2019 through April 30, 2019

- Email: 55%
- Network Server: 19%
- EMR: 3%
- Desktop Computer: 3%
- Laptop: 3%
- Paper Records: 16%
- Portable Electronic Device: 5%
- Other: 10%

BREACHES AFFECTING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED INVOLVING THE THEFT OF PHI

Calendar Years 2014 - 2018

- 2014: 331
- 2015: 30
- 2016: 30
- 2017: 56
- 2018: 40
General HIPAA Enforcement Highlights

• Expect to receive over 26,000 complaints this year

• In most cases, entities able to demonstrate satisfactory compliance through voluntary cooperation and corrective action

• In some cases, the nature or scope of indicated noncompliance warrants additional enforcement action

• Resolution Agreements/Corrective Action Plans
  — 60 settlement agreements that include detailed corrective action plans and monetary settlement amounts

• 4 civil money penalties

As of April 30, 2019
2018 Enforcement Actions

<table>
<thead>
<tr>
<th>Date</th>
<th>Organization</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/2018</td>
<td>Fresenius Medical Care North America</td>
<td>$3,500,000</td>
</tr>
<tr>
<td>2/2018</td>
<td>Filefax</td>
<td>$100,000</td>
</tr>
<tr>
<td>6/2018</td>
<td>University of Texas MD Anderson Cancer Center (CMP)</td>
<td>$4,348,000</td>
</tr>
<tr>
<td>9/2018</td>
<td>Boston Medical Center</td>
<td>$100,000</td>
</tr>
<tr>
<td>9/2018</td>
<td>Brigham and Women's Hospital</td>
<td>$384,000</td>
</tr>
<tr>
<td>9/2018</td>
<td>Massachusetts General Hospital</td>
<td>$515,000</td>
</tr>
<tr>
<td>10/2018</td>
<td>Anthem</td>
<td>$16,000,000</td>
</tr>
<tr>
<td>11/2018</td>
<td>Allergy Associates of Hartford</td>
<td>$125,000</td>
</tr>
<tr>
<td>12/2018</td>
<td>Advanced Care Hospitalists</td>
<td>$500,000</td>
</tr>
<tr>
<td>12/2018</td>
<td>Pagosa Springs Medical Center</td>
<td>$111,400</td>
</tr>
<tr>
<td>12/2018</td>
<td>Cottage Health</td>
<td>$3,000,000</td>
</tr>
</tbody>
</table>

Total $28,683,400

Recurring Compliance Issues

- Business Associate Agreements
- Risk Analysis
- Failure to Manage Identified Risk, e.g. Encrypt
- Lack of Transmission Security
- Lack of Appropriate Auditing
- No Patching of Software
- Insider Threat
- Improper Disposal
- Insufficient Data Backup and Contingency Planning
- Individual Right to Access
Corrective Actions May Include:

• Updating risk analysis and risk management plans
• Updating policies and procedures
• Training of workforce
• CAPs may include 3rd party or outside monitoring

Some Best Practices:

• Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and address breach/security incident obligations
• Risk analysis and risk management should be integrated into business processes; conducted regularly and when new technologies and business operations are planned
• Dispose of PHI on media and paper that has been identified for disposal in a timely manner
• Incorporate lessons learned from incidents into the overall security management process
• Provide training specific to organization and job responsibilities and on regular basis; reinforce workforce members’ critical role in protecting privacy and security
HITECH Audit Program

Purpose:
Identify best practices; uncover risks and vulnerabilities not identified through other enforcement tools; encourage consistent attention to compliance
**History**

- HITECH legislation: HHS (OCR) shall provide for periodic audits to ensure that covered entities and business associates comply with HIPAA regulations. (Section 13411)

- Pilot phase (2011-2012) – comprehensive, on-site audits of 115 covered entities

- Evaluation of Pilot (2013) – issuance of formal evaluation report of pilot audit program

- Phase 2 (2016-2017) - desk audits of 207 covered entities and business associates

**Phase 2 - Selected Desk Audit Provisions**

- For Covered Entities:
  - Security Rule: risk analysis and risk management; and
  - Breach Notification Rule: content and timeliness of notifications; or
  - Privacy Rule: NPP and individual access right

- For Business Associates:
  - Security Rule: risk analysis and risk management and
  - Breach Notification Rule: reporting to covered entity

- See auditee protocol guidance for more details:
Status

• 166 covered entity and 41 business associate desk audits were completed in December 2017

• Website updates with summary findings will be published in 2019

http://www.hhs.gov/hipaa

Join us on Twitter @hhsocmr
Brief on New NIST Privacy Framework Development

Presented and materials prepared by:

ELLEN NADEAU
Deputy Manager
Privacy Framework
National Institute of Standards and Technology (NIST)
Washington, D.C.
**Why NIST?**

- Long track record of successfully, collaboratively working with public and private sectors
- Experience developing the Cybersecurity Framework
- Extensive privacy expertise

---

**Process to Date**

- **Workshop #1**
  - Oct 16, 2018
  - Austin, TX
- **Request for Information (RFI)**
  - Nov 14, 2018 – Jan 14, 2019
- **RFI Analysis & Framework Outline**
  - Feb 27, 2019
- **Framework Discussion Draft**
  - Apr 30, 2019
- **Workshop #2**
  - May 13-14, 2019
  - Atlanta, GA

**ONGOING ENGAGEMENT**

Feedback encouraged and promoted throughout the process
NIST Privacy Framework: What is it?

Attributes:
- voluntary
- risk- & outcome-based
- non-prescriptive
- accessible language
- adaptable
- compatible with legal regimes

Enterprise risk management tool to help organizations answer the fundamental question: “How are we considering the privacy impacts to individuals as we develop our systems, products, and services?”

Future state:
NIST Privacy Framework version 1.0

Framework Development Stages

Working Outline – February 2019

Discussion Draft – April 2019

Preliminary Draft – Anticipated July/August 2019

Version 1.0 – Anticipated Late 2019
Upcoming Opportunities to Engage

Getting to V1.0 of the NIST Privacy Framework: Workshop #3
July 8-9, 2019 | Boise, Idaho

Review of NIST Privacy Framework Discussion Draft
**Relationship Between Cybersecurity and Privacy Risk**

- **Cybersecurity Risks**: arise from unauthorized activity.
- **Privacy Risks**: arise as a byproduct of authorized data processing.
- There is a clear recognition that security of data plays an important role in the protection of privacy.
- Individual privacy cannot be achieved solely by securing data.
- Authorized processing: system operations that handle data (collection - disposal) to enable the system to achieve mission/business objectives.

---

**Key Definitions**

*For the purposes of the Privacy Framework:*

**Data**
A representation of information with the potential for adverse consequences for individuals when processed.

**Data Processing**
Complete data life cycle, including but not limited to: collection, retention, logging, generation, transformation, use, disclosure, transfer, and disposal.

**Privacy Risk**
The likelihood that individuals will experience problems resulting from data processing, and the impact should they occur.
Relationship between Privacy Risk Management and Risk Assessment

Privacy risk assessments:

“...can help organizations make ethical decisions and avoid losses of trust that damage their reputations or slow adoption or cause abandonment of products and services.”

Appendix D: Key Privacy Risk Management Practices

- Organizing Preparatory Resources
- Determining Privacy Capabilities
- Defining Privacy Requirements
- Conducting Privacy Risk Assessments
- Creating Privacy Requirements Traceability
- Monitoring Changing Privacy Risks
Privacy Framework Structure

a set of privacy protection activities & desired outcomes that enables communication across the organization

representation of the current and target privacy outcomes the organization is focused on

how an organization views privacy risk and whether it has adequate processes & resources in place to manage that risk

Core Functions

- **Identify (ID)**: Develop the organizational understanding to manage privacy risk for individuals arising from data processing or their interactions with systems, products, or services.
- **Protect (PR)**: Develop and implement appropriate data processing safeguards.
- **Control (CT)**: Develop and implement appropriate activities to enable organizations or individuals to manage data with sufficient granularity to manage privacy risks.
- **Inform (IN)**: Develop and implement appropriate activities to enable organizations and individuals to have a reliable understanding about how data are processed.
- **Respond (RS)**: Develop and implement appropriate activities to take action regarding a privacy breach or event.
## Example Core Categories

<table>
<thead>
<tr>
<th>ID</th>
<th>PR</th>
<th>CT</th>
<th>IN</th>
<th>RS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID</td>
<td>PR</td>
<td>CT</td>
<td>IN</td>
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<tr>
<td>ID</td>
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<tr>
<td>ID</td>
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</tr>
<tr>
<td>ID</td>
<td>PR</td>
<td>CT</td>
<td>IN</td>
<td>RS</td>
</tr>
</tbody>
</table>

**Example Core Categories**

<table>
<thead>
<tr>
<th>ID</th>
<th>PR</th>
<th>CT</th>
<th>IN</th>
<th>RS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID.IM-P</td>
<td>PR.PP-P</td>
<td>CT.DM-P</td>
<td>IN.AW-P</td>
<td>RS.RE-P</td>
</tr>
</tbody>
</table>

### Data Processing and Individuals’ Interactions with Systems, Products, or Services are Understood and Inform the Management of Privacy Risk.

Data processing and individuals’ interactions with systems, products, or services are understood and inform the management of privacy risk.

### Technical Data Processing Solutions Increase Disassociability Consistent with Related Policies, Procedures, and Agreements and the Organization’s Risk Strategy to Protect Individuals’ Privacy.

Technical data processing solutions increase disassociability consistent with related policies, procedures, and agreements and the organization’s risk strategy to protect individuals’ privacy.

### Data Management

Data are managed consistent with the organization’s risk strategy to protect individuals’ privacy and increase manageability.

### Data Processing Awareness

Individuals and organizations have an awareness of data processing practices, and processes and procedures are used and maintained to increase predictability consistent with the organization’s risk strategy to protect individuals’ privacy.

### Redress

Organizational response activities include processes or mechanisms to address impacts to individuals that arise from data processing.

## Example Core Subcategories

<table>
<thead>
<tr>
<th>ID</th>
<th>PR</th>
<th>CT</th>
<th>IN</th>
<th>RS</th>
</tr>
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<tbody>
<tr>
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<td>CT</td>
<td>IN</td>
<td>RS</td>
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<tr>
<td>ID</td>
<td>PR</td>
<td>CT</td>
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<td>RS</td>
</tr>
<tr>
<td>ID</td>
<td>PR</td>
<td>CT</td>
<td>IN</td>
<td>RS</td>
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</table>

**Example Core Subcategories**

<table>
<thead>
<tr>
<th>ID</th>
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<th>IN</th>
<th>RS</th>
</tr>
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<tbody>
<tr>
<td>ID</td>
<td>PR</td>
<td>CT</td>
<td>IN</td>
<td>RS</td>
</tr>
</tbody>
</table>

### Data are Processed to Limit the Identification of Individuals.

Data are processed to limit the identification of individuals.

### Data Elements Can Be Accessed for Deletion.

Data elements can be accessed for deletion.

### Data Analytic Inputs and Outputs Are Understood and Evaluated for Bias.

Data analytic inputs and outputs are understood and evaluated for bias.

### Processes for Receiving and Responding to Complaints, Concerns, and Questions from Individuals about Organizational Privacy Practices are in Place.

Processes for receiving and responding to complaints, concerns, and questions from individuals about organizational privacy practices are in place.
Privacy Framework Profiles

organizational or industry sector goals

legal/regulatory requirements & industry best practices

organization's risk management priorities

the privacy needs of individuals

Profile

Identify
Protect
Control
Inform
Respond

Current and Target Profiles

Current Profile

Identify
Protect
Control
Inform
Respond

Target Profile

Identify
Protect
Control
Inform
Respond

- identify gaps
- develop an action plan for improvement
- gauge the resources that would be needed (e.g., staffing, funding) to achieve privacy outcomes
**Implementation Tiers**

<table>
<thead>
<tr>
<th>Understanding Privacy Risks</th>
<th>Resources and Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the privacy risks you need to manage as an organization?</td>
<td>Do you have the adequate resources and processes in place to manage these risks?</td>
</tr>
</tbody>
</table>

**Implementation Tiers**

- 1: Partial
- 2: Risk Informed
- 3: Repeatable
- 4: Adaptive

Where are you in terms of having resources and processes and where do you want to be?

**How to Use the Privacy Framework**

- Strengthening Accountability
- Basic Review of Privacy Practices
- Establishing or Improving a Privacy Program
- Application in the System Development Life Cycle
- Communicating Privacy Requirements with Stakeholders
- Informative References
Informative References

- Specific sections of standards, guidelines, and practices that can be mapped to the Core subcategories and support achievement of the subcategory outcomes
- NIST has provided a mapping of the Core subcategories to relevant NIST guidance
- NIST will develop a process for accepting external informative references

Roadmap
Resources

Website
https://nist.gov/privacyframework

Mailing List
https://groups.google.com/a/list.nist.gov/forum/#!forum/privacyframework

Contact Us
PrivacyFramework@nist.gov
@NISTcyber #PrivacyFramework

Presented and materials prepared by:

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Chief Equity and Inclusion Officer
Children's Minnesota
Minneapolis

The 2019 Health Law Institute – June 20, 2019

James C. Burroughs
Chief Equity and Inclusion Officer
Children’s Minnesota

I.D.E.A.S.
Inclusion - Diversity – Equity – Access - Solutions
Bright I.D.E.A.S.
Can’t We All Just Get Along
No!

• “People fail to get along because they fear each other; they fear each other because they don’t know each other; they don’t know each other because they have not communicated with each other.”
  — Martin Luther King, Jr.

CEO Equity and Inclusion Commitment

Our vision at Children’s Minnesota:
• Be every family’s essential partner in raising healthier children;
• Eliminate health disparities;
• Workforce is as diverse as the families we serve;
• Inclusive and safe environment where every employee feels valued for the differences and similarities they bring; and
• Incorporate equity and inclusion in everything we do;

Marc Gorelick, President and Chief Executive Officer, Children’s Minnesota
CEO Health Equity Commitment

• Health disparities arise from the same issues of historical oppression and systemic racism that underlie a host of other issues;

• Referring people to food banks and educating doctors about pain protocols is like giving ibuprofen to someone with an infection; it treats the symptom, not the disease.

Marc Gorelick, President and Chief Executive Officer, Children’s Minnesota

Why We Must Get it Right

• Minnesota - 1990 – 6% population People of Color and Native American; 2019 – 19% population people of color and Native American

• By 2035, according to the Minnesota State Demographic Center, populations of color are expected to continue to increase faster than the white non-Hispanic population, increasing to 25 percent of the total state population.

• By 2050 1 out of 2 working age Minnesotans will be Persons of Color or Native American.

• Twin Cities ranks 4th worst metro area for Black people in the United States.

• Census Bureau Minnesota population growth (July, 2010 - July, 2017)
  − White population: 1 percent increase
  − Black population: 31 percent increase
  − Asian population: 30 percent increase
  − Latino population: 20 percent increase
Why We Must Get it Right

- 47% Patients of Color and Native American
- 7% Health Care Professionals of Color and Native American
- 10% Leaders of Color and Native American
- 19% Employees of Color and Native American
  - (80% of Service workers (janitor, kitchen, material handlers)
  - What is the % of MEC that’s are Persons of Color and Native Americans

Structural/Institutional Racism

Structural Racism is embedded in our historical, political, cultural, social, and economic systems and institutions. Structural Racism systematically disadvantages people of color and has a negative impact on other marginalized populations.

Structural/Institutional Racism produces:

- Racial Inequity and adverse outcomes for people of color (e.g. health, wealth, careers, education, infrastructure and civic participation)
- Unfair and unjust practices that limit participation and prosperity of people of color

Source: PolicyLink, “The Competitive Advantage of Racial Equity”
https://www.policylink.org/sites/default/files/The%20Competitive%20Advantage%20of%20Racial%20Equity-final_0.pdf
Structural/Institutional Racism

- Residential Segregation (Zip Code, Poverty, Education, Environment and Infectious Agents)
- Childhood/Generational Trauma (policing, slavery, genocide and internment)
- HR Policies (Experience and Education)
- “Good Fit”
- Affordable Housing, Unemployment, Educational Outcomes, Healthy Food and Livable Wages

Racial Equity

Racial Equity is when:

- Race no longer determines one’s outcomes (e.g. health, wealth, careers, education, infrastructure and civic participation);
- Everyone has what they need to thrive, no matter where they live;
- Those most impacted by structural racial inequity are meaningfully involved (e.g. owners, planners and decision makers) in the creation and implementation of the institutional policies and practices that impact their lives; and
- We acknowledge and account for past and current inequities

Source: Center for Social Inclusion
https://www.centerforsocialinclusion.org/our-work/what-is-racial-equity/
I.D.E.A.
Inclusion – Diversity – Equity – Access - Solutions

Inclusion
• All employees, vendors, community partners, patients and families feel valued, respected, and supported; and
• Everyone can bring their full selves to work or via a partnership and fully engage and connect.

Diversity
• Diversity reflects the ways in which we are different and the ways we are the same;
• Our goal is to have a workforce, vendors, community partners, patients and families that reflect the rich diversity within the State; and
• Primary dimensions of focus of diversity at Children’s will be race, ethnicity, religion, sexual orientation, gender identity, physical ability, veteran status and gender.
I.D.E.A.
Inclusion – Diversity – Equity – Access - Solutions

Equity
• Provide all employees, vendors, community partners, patients and families what they need to be successful;
• Create access and opportunity for all employees to do their best work and reduces and eventually eliminates barriers to workplace success;
• Create access and opportunity for vendors, community partners, patients and families to be valued and included in order to receive high quality service and care; and
• Eliminate Health Disparities

Access
• Provide access and use of quality employment, contracting, partnerships and services for all;
• Increase access and opportunity for traditionally underutilized and underserved populations; and
• Provide quality service and resources in order to make access meaningful and result in equitable outcomes.
I.D.E.A.
Inclusion – Diversity – Equity – Access - Solutions

Solutions
• Equity requires actions!
• Solutions require problem solving! (The Table)
• Actions must be geared towards solutions!
• Solutions will be painful!
• Solutions must be sustainable!
• Solutions must be shared!

Strategic Vision
Equity Framework – The Cure
Connecting the I.D.E.A.S and The Cure!

- How are your equity and inclusion goals connected to the mission and vision?
- Who is responsible for integrating these goals into the mission and vision?
- What are the strategies for integrating these goals into the mission and vision?
- What does success look like? How will you know integration has been accomplished?

Social Determinants of Health

Conditions in the places where people live, learn, work, and play affect a wide range of health risks and outcomes. These conditions are known as Social Determinants of Health (SDOH).

Centers for Disease and Control Prevention

The World Health Organization (WHO) offers this definition of social determinants of health: “The conditions in which people are born, grow, live, work and age.”
Social Determinants of Health

Income level
Educational opportunities
Occupation, employment status, and workplace safety
Gender inequity
Racial segregation
Food insecurity and inaccessibility of nutritious food choices
Access to housing and utility services
Early childhood experiences and development

Social Determinants of Health

Social support and community inclusivity
Crime rates and exposure to violent behavior
Availability of transportation
Neighborhood conditions and physical environment
Access to safe drinking water, clean air, and toxin-free environments
Recreational and leisure opportunities

NEJM – Catalyst, Patient Engagement
Equity and Inclusion
Institute for Healthcare Improvement
Performance Measures (PM)

- Health Equity Assessment Secondary Performance Measures
- 2019 Operations Plan Target
  - 2018 - 4 out of 19 PMs
  - 2019 - 9 out of 18 PMs
- Performance Measure Selection Process
  - Health Equity Self Assessment
  - Health Equity Council PM Ranking
  - Health Equity Council Work Groups

Equity and Inclusion
Institute for Healthcare Improvement
Performance Measures – 9 out of 18

1. Are there practices in place to recruit, retain, and develop employees at all levels?
2. Is there training for staff to help identify equity and disparity gaps?
3. Are there dedicated resources to support health equity work? Is there sustainable funding for health equity work?
4. Are we using disparity data to drive work for health equity improvements?
Equity and Inclusion
Institute for Healthcare Improvement
Performance Measures – 9 out of 18

5. Are we working in partnership with others in the community to improve health equity for the population?
6. Is there a standard process to collect and analyze REAL data?
7. Are our facilities welcoming to the community?
8. Is leadership committed to improving equity at all levels?
9. Is there involvement to improve healthy behaviors for employees and the community as a whole?

Equity and Inclusion
Institute for Healthcare Improvement
Performance Measures

- Are we incorporating elements of physical design to reduce institutional racism?
- Is health equity a strategic priority for the organization?
- Is there a governance structure to support work on health equity?
- Are there practices in place to encourage diverse supplier procurement processes?
Equity and Inclusion
Institute for Healthcare Improvement
Performance Measures – Work Groups

• Accountability and Measurement
• Policy Review (HR)
• Patient Quality & Experience Improvement and Employee Engagement
• Training and Awareness
• Community Engagement
Provider Privacy Hotspots: Social Media, Proactive Monitoring, and Genetic Information

Presented and materials prepared by:

APRIL CARLSON
Privacy Officer & Data Protection Officer
Mayo Clinic
Rochester
Provider Privacy Hotspots:
Social Media, Proactive Monitoring, and Genetic Information

Privacy

• Social Media Breach Trends (Importance of Compliance Hotline)
  o Snapchat
  o Instagram
  o Facebook

• Proactive Privacy Monitoring Program
  o High Profile Patients
  o Local Notoriety Patients (Google alerts)
  o Neighbors (same street)
  o Coworkers (same work unit)
  o Family Members (generally lower risk)
• Genetic Information
  
  o GDPR
  
  o Safe Harbor De-identification (18 identifiers)
  
  o Statistical De-identification
    
    ▪ Likelihood of re-identification based on recipient

Security

• Personal Devices/Internet of Things (IoT)
  
• Portable Ultrasound Devices
  
• Patients taking photos/streaming video
  
• Departments monitoring/recording patients

Open Discussion Q & A
2019 Healthcare Litigation Update

Presented and materials prepared by:

CAITLYN FRANCOIS
Director of Public Policy
Medica
Minnetonka

ARCHANA NATH
Fox Rothschild LLP
Minneapolis
2019 Healthcare Litigation Update

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Although this outline is intended to serve as an overview of the key federal litigation related to the insurance provisions of the Affordable Care Act, individuals wanting to know more about other ACA-related litigation, including pleadings and supporting documents, can access them on https://affordablecareactlitigation.com/. Please also see the written materials for the “2018-2019 ACA Litigation Review: Straining the Acronym Soup” session for more information about ACA cases.

This outline is accurate as of May 22, 2019

---

1 Patient Protection and Affordable Care Act, Public Law 111-148.
I. ACA Cases

A. ACA Section 1557 Nondiscrimination Cases

Section 1557 of the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. Under subparagraph (c), the Secretary of the Department of Health and Human Services may promulgate regulations to implement these nondiscrimination requirements. On May 18, 2016, the Office for Civil Rights published a final rule implementing Section 1557, and interpreted the phase “on the basis of sex” to include gender identity. OCR further defined “gender identity” to mean “an individual’s sense of gender, which may be different from an individual’s sex assigned at birth.”

There have been several lawsuits on ACA Section 1557.

Status: After lifting the stay, briefings on the cross-motions for summary judgment in Franciscan Alliance are due May 24, 2019.

Summary: On August 23, 2018, Franciscan Alliance, two other health care providers, and five states, led by Texas, filed a lawsuit in the U.S. District Court of Northern Texas, seeking to invalidate the 1557 final rule and permanently enjoin enforcement of the final rule. On December 31, 2016, Judge Reed O’Connor issued an order granting the plaintiffs’ request for preliminary injunction, and enjoined the Administration from enforcing the final rule’s prohibition against discrimination on the basis of gender identity or termination of pregnancy.

Judge O’Connor found that the statutory text of Section 1557 clearly incorporated Title IX’s prohibition on sex discrimination. The next question was what constitutes Title IX sex discrimination, and Judge O’Connor noted “this Court has previously concluded: the meaning of sex in Title IX unambiguously refers to ‘the biological and anatomical differences between male and female students as determined at their birth.’” Congress “clearly addressed the question at

---

2 42 U.S.C. § 18116 (“Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.”).

3 Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31376 at 31397 (May 18, 2016).
4 Id. at 31384.
7 Id. at 671.
issue by incorporating Title IX’s existing legal structure,” and thus, *Chevron* deference did not apply to the final rule because HHS had no authority to interpret beyond Congress’s intent.\(^9\)

On May 2, 2017, the Trump Administration filed a motion for a voluntary remand and stay, requesting that HHS have the opportunity to reconsider the regulation.\(^10\) Judge O’Connor granted the motion, requiring periodic status reports, and clarified that the preliminary injunction was still in effect.\(^11\) On April 13, 2018, HHS submitted a proposed rule entitled “Nondiscrimination in Health Programs and Activities” to OMB for final regulatory review.\(^12\)

In December 2018, Judge O’Connor lifted the stay and set a new briefing schedule at the request of the plaintiffs and defendants.\(^13\) Pleadings on the cross-motions for summary judgment are due May 24, 2019.\(^14\)

**Implications:** Given recent administrative actions regarding religious and moral exemptions and accommodations, protections for statutory conscience rights, and the DOJ’s withdrawal of guidance on Title IX,\(^15\) it seems likely that the anticipated proposed regulations on Section 1557 nondiscrimination will look substantially different from the 2016 final rule.\(^16\)

In other cases, despite the nationwide injunction, Courts have looked at Section 1557 rather than OCR’s interpretation of the statute, and come to differing conclusions. *See Tovar v. Essentia Health*, 342 F.Supp. 3d, 947 (Sep. 20, 2018) (holding that Section 1557 prohibits discrimination dismissed (Mar. 30, 2016) (“Title IX does not prohibit discrimination on the basis of transgender itself because transgender is not a protected characteristic under the statute.”).

\(^9\) Id.


\(^13\) Id. (“Although HHS is currently reevaluating the reasonableness, necessity, and efficacy of the Rule, the time required to complete the notice-and-comment phase and to publish a final rule is not currently known, ECF No. 119 at 2 (Status Report #7), and may take a substantial length of time. Proposed intervenors also desire a final ruling on their motion to intervene. Accordingly, the parties agree that the Court should lift the stay of this litigation, resolve the motion to intervene, and allow the parties to file motions for summary judgment.”).


\(^16\) An advanced copy of the proposed regulations was released on May 24, 2019. Nondiscrimination in Health and Health Education Programs or Activities; Proposed Rule (May 24, 2019), available at https://www.hhs.gov/sites/default/files/1557-nprm-hhs.pdf.
based on gender identity based on the plain, unambiguous language of the statute, and the resolution of *Franciscan Alliance*, or any new regulation, would not affect the District Court’s holding that the plaintiff was discriminated against because of his gender identity); and *Flack v. Wis. Dept. of Health Servs.*, 328 F.Supp. 3d 931 (July 25, 2018) (holding that the state’s Medicaid regulation denying coverage for gender reassignment surgery and related drugs violated Section 1557, but “[t]he court recognizes that granting preliminary relief alters the status quo, if barely so, given the present uncertainty about the requirement of coverage under federal regulation”).

**Other Applicable Cases:**

- Audia v. Briar Place, Ltd., No. 1:17-cv-6618 (May 9, 2019) (N.D. Ill.) (settled)
- Boyden v. Conlin, 341 F.Supp. 3d 979 (Sep. 18, 2018) (summary judgment for plaintiff granted)
- Condry v. United Health Group, Inc., No. 1:17-cv-183 (Jun. 27, 2018) (N.D. Cal.)
- Doe One v. CVS Pharmacy, Inc., 348 F.Supp. 3d 967 (Dec. 12, 2018) (N.D. Cal.)
- Doe v. BlueCross BlueShield of Tennessee, Inc., No. 2:2017-cv-02793 (July 30, 2018) (W.D. Tenn.) (motion to dismiss granted; dismissed with prejudice)
- Esparza v. University Medical Center Management Corp., No. 2:17-cv-4803 (Sep. 5, 2017) (E.D. La.)
- E.S. v. Regence BlueShield, No. 2:17-cv-1609 (Sep. 24, 2018) (W.D. Wash.) (dismissed and appealed to Ninth Circuit)
- Smith v. Highland Hospital of Rochester, No. 17-cv-6781 (Oct. 2, 2018) (W.D. N.Y.) (motion to dismiss granted, plaintiff appealed to Second Circuit)
- Hardford Healthcare Corp. v. Anthem, No. 3:17-cv-1686 (Nov. 1, 2017) (D. Conn.) (motion to dismiss granted)
- Prescott v. Rady Children’s Hospital, No. 3:16-cv-2408 (Feb. 27, 2019) (S.D. Cal.) (motion to dismiss granted in part and denied in part; amended complaint)
B. Premium Stabilization and Affordability Programs Cases

Cost-sharing reductions (“CSRs”) help reduce deductibles, copayments, coinsurance, and out-of-pocket maximums for lower-income qualified health plans enrollees. Section 1402 of the ACA requires qualified health plan issuers to provide CSRs to eligible low-income marketplace consumers. The federal government reimburses qualified health plan issuers in the individual market for the cost of providing CSRs.

In 2017, after the latest presidential election and the failed attempts to repeal and replace the ACA, HHS released a memo to health insurance issuers, supported by a legal opinion from then-Attorney General Jeff Sessions, which stated CSR payments to issuers would cease immediately.

The ACA also included three programs intended to stabilize premiums in the individual and small group markets: transitional reinsurance, permanent risk adjustment, and temporary risk corridors. There are several federal lawsuits related to two of these programs: risk adjustment and risk corridors.

The purpose of the risk adjustment program is to reduce or eliminate the impact of risk selection by redistributing funds from plans with lower-risk enrollees to plans with higher-risk enrollees. According to the American Academy of Actuaries:

The [risk adjustment] program transfers money among insurers based on the risks of the people they enroll and the average premium collected within the state for all insurers. Insurers with a relatively healthier enrollee population contribute to a fund that makes payments to those insurers with a relatively sicker enrollee population. The risk adjustment program is designed to be revenue-neutral within each state.

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19 45 CFR § 156.430(b)(1) (“A QHP issuer will receive periodic advance payments based on the advance payment amounts calculated in accordance with § 155.1030(b)(3) of this subchapter”).
20 Letter from Eric Hargan, Acting Secretary, to Seema Verma, Administration of Ctrs. For Medicare & Medicaid Servs. (Oct. 12, 2017), available at https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf (“In light of that opinion – and the absence of any other appropriation that could be used to fund CSR payments – CSR payments to issuers must stop, effective immediately. CSR payments are prohibited unless and until a valid appropriation exists.”).
That is, transfer payments from insurers with a relatively healthier population equal
transfer payments to insurers with a relatively sicker population. 22

The risk corridors program was intended to promote accurate premiums in the early years of
implementation by discouraging individual market issuers from setting premiums too high to
reduce uncertainty or too low to buy-up market share. 23 Under the risk corridors program, the
federal government would provide funding if a health plan’s losses exceeded a certain threshold,
and a health plan would pay the federal government if its gains exceeded a certain threshold. 24

1. Cost-Sharing Reduction Cases

Status: The U.S. District Court for D.C. found that Congress had not sufficiently appropriated
funds for CSRs.

HHS reached a settlement with Minnesota and New York over the financial impacts to their Basic
Health Programs.

There are at least twelve cases filed in the Court of Federal Claims by insurers seeking recovery
Co-Op and Sanford Health Plan have been consolidated into one case, and the Administration
filed its opening brief on March 22, 2019.

Summary: There have been three types of lawsuits regarding CSRs: (1) Whether CSRs were
properly appropriated by Congress; (2) the impacts of CSR nonpayment on Basic Health
Programs; 25 and (3) Payment of CSRs to qualified health plan issuers.

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22 Insight on the ACA Risk Adjustment Program, AM. ACAD. OF ACTUARIES 3 (Apr. 2016), available at
23 Id.
24 Research Brief: Design and Implementation Considerations of ACA Risk-Mitigation Programs, AM. ACAD. OF
ACTUARIES available at https://www.actuary.org/sites/default/files/files/AAA-
SOA_research_brief_on_3Rs_060412.pdf. The following is an excerpt from Congressional testimony: “If actual
claims are within 3 percent of expected, insurers either keep the gains or bear the losses. If actual claims exceed
expected claims by more than 3 percent, the federal government reimburses the insurer for 50 percent of the losses
between 3 and 8 percent, and 80 percent of the losses exceeding 8 percent. If actual claims fall below expected claims
by more than 3 percent, the insurer pays the federal government for 50 percent of the gains between 3 and 8 percent,
and 80 percent of the gains exceeding 8 percent.” ObamaCare: Why the Need for an Insurance Company Bailout?
Before the H. Comm. on Oversight and Gov’t Reform, 113th Cong. (2014) (statement of Cori E. Uccello, Am. Acad.
25 Basic Health Programs are governed by ACA Section 1331 as a health benefits coverage program for low-income
residents who are not eligible for Medicaid and would otherwise be enrolled in qualified health plans. Basic Health
Basic Health Program is funding through a 95% match of the premium tax credits and cost-sharing reductions that
would have otherwise been provided to eligible individuals if they had enrolled in qualified health plans. Id.
1. Whether CSRs were Properly Appropriated by Congress

Federal litigation over CSR payments began in November 2014, when the U.S. House of Representatives sued HHS, arguing that CSR payments to insurers were improper because there was no specific congressional appropriation to make them. In 2016, Judge Rosemary Collyer agreed that CSR payments to issuers was enjoined until a valid appropriation was made, but she stayed the injunction pending appeal. House v. Burwell (which would ultimately be changed to House v. Azar) was appealed to the U.S. Court of Appeals for the D.C. Circuit by HHS. In the meantime, President Trump was elected, and the Trump administration ended CSR payments to issuers in October 2017. The parties to the litigation subsequently agreed that there was no need to resolve the lawsuit.

State attorneys general then filed a separate lawsuit, California v. Trump, against HHS for ending CSR payments to QHP issuers. The plaintiff states sought declaratory and injunctive relief to “compel President Trump and the federal agencies to make CSR reimbursement payments in accordance with the ACA and its permanent appropriation.” In July 2018, Judge Vince Chhabria of the U.S. District Court for the Northern District of California dismissed the case without prejudice.

2. The Impacts of CSR Nonpayment on Basic Health Programs

Minnesota and New York are the only states with approved Basic Health Program blueprints. On January 26, 2018, Minnesota and New York filed a lawsuit to challenge HHS’ “abrupt and unlawful cutoff of more than $1 billion annually in federal funding owed to the States to operate ‘Basic Health Programs’ (‘BHPs’).” In particular, the plaintiff states pointed to e-mails from HHS:

informing them that the agency would not be paying the $266 million due to New York and $32 million due to Minnesota for their BHP expenses in the first quarter of 2018—amounts that HHS described as the “CSR component” of the BHP.

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27 See supra note 19 (“In light of that opinion – and the absence of any other appropriation that could be used to fund CSR payments – CSR payments to issuers must stop, effective immediately. CSR payments are prohibited unless and until a valid appropriation exists.”).
payment. HHS’s sole justification for reducing its BHP payments, as articulated in these emails, was the federal government’s earlier decision in October 2017 to stop making CSR payments to insurers offering QHPs on exchanges.\textsuperscript{34}

On May 3, 2018, Judge Richard Sullivan approved a settlement between the parties,\textsuperscript{35} and HHS released its revised BHP funding methodology, providing an additional $422 million to New York and $46 million to Minnesota for their Basic Health Programs.\textsuperscript{36}

3. Payment of CSRs to Qualified Health Plan Issuers

In six of the twelve cases filed,\textsuperscript{37} including one class action (\textit{Common Ground HealthCare Cooperative v. U.S.}), the Court of Federal Claims granted the plaintiff insurers’ motions for summary judgment. The plaintiff insurers in these cases are seeking recovery of the CSR payments owed to issuers of qualified health plans in the individual market after the Federal Government ceased payments in October 2017.\textsuperscript{38} The Federal Government has appealed three of those cases (\textit{Montana Health Co-Op v. U.S.}, \textit{Sanford Health Plan v. U.S.}, and \textit{Community Health Choice v. U.S.}) to the Federal Circuit. \textit{Montana Health Co-Op} and \textit{Sanford Health Plan} have been consolidated into one case, and the Federal Government filed its opening brief on March 22, 2019.

\textbf{Implications:} These three types of cases show that careful legislative drafting is important, but also that administrative changes in interpretation will almost certainly lead to protracted litigation.

2. Risk Corridor Cases

\textbf{Status:} The Supreme Court is reviewing a petition for a writ of certiorari in \textit{Moda Health Plan Inc. v. United States},\textsuperscript{39} which is linked with \textit{Maine Community Health Options v. United States} and \textit{Land of Lincoln Mutual Health Insurance Co. v. United States}. The issue is “whether Congress can evade its unambiguous statutory promise to pay health insurers for losses already incurred simply by enacting appropriations riders restricting the sources of funds available to satisfy the government’s obligation.”\textsuperscript{40} Moda Health Plan, Blue Cross and Blue Shield of North Carolina, Land of Lincoln, and Maine Community Health Options filed their petitions on February 4, 2019;

\textsuperscript{34}Id. at 3.
\textsuperscript{36}Basic Health Program; Final Administrative Order, 83 Fed. Reg. 56328 at 56330 (Nov. 13, 2018).
\textsuperscript{37}For a comprehensive list of the various CSR lawsuits, see Cost Sharing Reductions Payments, AFFORDABLE CARE ACT LITIGATION (last visited May 21, 2019), https://affordablecareactlitigation.com/cost-sharing-reductions-payments/.
\textsuperscript{38}See supra note 20.
\textsuperscript{40}Id. at i.
the United States filed a brief in opposition on May 8, 2019. The insurers have one more opportunity to respond before the Supreme Court consider whether or not to accept the appeal.

**Summary:** The crux of the cases is whether Congress appropriated funds for making risk corridor payments or could use other HHS funds to help pay for risk corridor payments. In December 2014, Congress enacted an appropriations act for fiscal year 2015, and it included a provision that expressly prohibited the use of additional HHS funds to pay for the risk corridors program:

None of the funds made available by this Act from [CMS trust funds], or transferred from other accounts funded by this Act to the ‘Centers for Medicare and Medicaid Services—Program Management’ account, may be used for payments under section 1342(b)(1) of Public Law 111-148 [i.e., 42 U.S.C. 18062(b)(1)] (relating to risk corridors).

Congress reenacted the same prohibition in the 2016 and 2017 appropriations.

Several health insurers sued HHS for failing to make more than $12 billion in outstanding risk corridors payments. Health insurers sued in the Court of Federal Claims under the Tucker Act. In *Moda*, the Claims Court granted Moda partial summary judgment as to liability. Other similar suits in the Claims Court had mixed results. The Federal Circuit Court reversed the *Moda* decision on June 14, 2018, holding the statute created an obligation of the government to pay exchange participants the amount indicated by the statutory formula, but the Congressional appropriations bills repealed or suspended HHS’ obligation to make payments. The Federal Circuit Court found that no statement by the government evinced an intent to form a contract.

**Implications:** Due to the retroactive calculation of risk corridor payments, health insurers offering exchange coverage in the individual market were unable to account for Congress’ appropriation instructions in their product pricing. The results of any Supreme Court decision, if it grants cert, may have political implications, as noted by Timothy Jost: “There is a real problem as to the government’s willingness and ability to make good on its promises going forward.”

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46 Id. at 1330.
47 Many insurers, including co-ops formed under the ACA, went out of business because of their inability to collect risk corridor payments. How the ACA ‘Risk Corridor’ Fallout is Hurting Health Care, KNOWLEDGE @ WHARTON, (Mar. 29, 2018), available at https://knowledge.wharton.upenn.edu/article/significance-risk-corridors-lawsuits/ (summarizing statements by Tim Jost).
forward.” Additional health insurers, not party to the *Moda* or *Land of Lincoln* may have their opportunity for recovery: *Health Republic Insurance Company v. United States*, a class action seeking recovery of risk corridor payments, was stayed pending a final decision in *Moda* and *Land of Lincoln*.

**Other Applicable Cases:**

- Hammer v. U.S. Dep’t of Health & Human Servs., No. 18-2583 (7th Cir.) (Sep. 25, 2018)

3. **Risk Adjustment Cases**

New Mexico Health Connections, a New Mexico Co-Op health plan, filed two lawsuits alleging HHS did not follow the Administrative Procedures Act when adopting the use of the statewide average premium to maintain budget neutrality in the federal ACA risk adjustment program.49

**Status:** On appeal to the Tenth Circuit Court of Appeals. New Mexico Health Connections filed a brief, which did not request oral arguments, on April 22, 2019. The Administration’s reply brief is due June 3, 2019.50

**Summary:** This case involves a challenge to HHS’ policy of using a statewide average premium in its 2014-2018 risk adjustment regulations. Early in 2018, U.S. District Court Judge James Browning issued a decision setting aside and vacating that policy for the 2014-2018 benefit years because they agency failed to sufficiently explain its rationale and remanded back the agency to revisit its rulemaking. The judge in the New Mexico case previously indicated that HHS could pursue rulemaking to explain its rationale for adopting the statewide average premium.51 This

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48 *Id.*


51 “Nevertheless, HHS could have justified its promulgation of budget neutral regulations if it determined that budget neutrality was a worthy policy goal. HHS never made such a determination in the record, however, and the Court considers only the reasons that the agency actually gave and not the reasons that the agency might have given when determining agency action was arbitrary and capricious.” New Mexico Health Connections v. U.S.s Dep’t of Health & Human Servs., 312 F. Supp. 3d 1164 at 1205 (Feb. 28, 2018).
ruling came after a U.S. District Court of Massachusetts found that HHS acted within its authority in adopting the statewide average premium.\textsuperscript{52}

HHS filed a motion in March 2018, to alter or amend the judgment. A hearing was held in June, and HHS asked the court to use its discretion to remand the rule to HHS without vacating it, or to limit the impact to New Mexico. Shortly thereafter, HHS released a press statement that it would be delaying the 2017 risk adjustment payments and collection.\textsuperscript{53} On July 24, 2018, HHS released a final rule on 2017 risk adjustment program. HHS previously adopted the methodology for the 2019 risk adjustment program, and explained its rationale for adopting the statewide average premium.\textsuperscript{54} Judge Browning declined to alter or amended the original March 2018 judgment,\textsuperscript{55} and HHS appealed the decision to the Tenth Circuit Court of Appeals on December 14, 2018.\textsuperscript{56} In the meantime, HHS also released a proposed rule on the 2018 risk adjustment program.\textsuperscript{57}

Shortly after the release of the release of the final rule on the 2017 risk adjustment program, New Mexico Health Connections filed a second lawsuit on August 13, 2018, alleging that the 2017 final rule also violated the Administrative Procedures Act.\textsuperscript{58} That case was reassigned to Judge Browning and is currently stayed. On November 2, 2018, the judge continued the stay of the case pending a further status report by the parties. On January 28, 2019, the parties filed a joint status report that included a request to stay proceedings until the appeal in the lawsuit challenging the 2014-2018 risk adjustment regulations is resolved. The Court has not responded.

New Mexico Health Connections filed its appellate brief to the Tenth Circuit on April 22, 2019.\textsuperscript{59} New Mexico Health Connections reasserts its argument: HHS was arbitrary and capricious in finalizing regulations for the ACA risk adjustment program which use a statewide average premium to maintain budget neutrality, and that vacating the regulations was the appropriate remedy.

**Implications:** The litigation opened questions about how health insurers were supposed to account for expected, but not received, risk adjustment payments in their medical loss ratio reports, as well

\textsuperscript{54} Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 83 Fed. Reg. 16930 at 16954 (Apr. 17, 2018).
\textsuperscript{57} Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit year; Proposed Rule, 83 Fed. Reg. 39644 (Aug. 10, 2018).
as whether CMS would require health insurers to unwind the payments and collections made for the 2014, 2015, and 2016 benefit years.

C. Medicaid Work Requirements

**Status:** The Kentucky and Arkansas work requirement cases have been appealed to the D.C. Circuit. Final briefs are due August 1, 2019.\(^{60}\)

**Summary:** *Stewart v. Azar,\(^{61}\) Gresham v. Azar,\(^{62}\) and Philbrick v. Azar,\(^{63}\)* involve challenges to HHS-approved state 1115 Medicaid waivers that impose, among other things, work requirements. On March 27, 2019, U.S. District Court Judge James Boasberg vacated HHS’ approval of Kentucky’s (Stewart) and Arkansas’ (Gresham) Medicaid 1115 waivers, which included work requirements\(^{64}\) for recipients. The judge found that the Federal Government failed to justify that adding employment conditions advanced the programs’ basic purpose of providing health coverage. The plaintiffs argued that Medicaid is a health insurance program, and work requirements are contrary to Medicaid’s purpose if they reduce individuals’ access to the coverage.

In *Stewart*, Judge Boasberg found that HHS “never once mentions the estimated 95,000 people who would lose coverage, which gives the Court little reason to think that he seriously grappled with the bottom-line impact on healthcare.”\(^{65}\) Judge Boasberg held the approval of Kentucky’s waiver invalid *in toto*, and remanded the case back to HHS for another determination.\(^{66}\) HHS subsequently reapproved the program in November 2018, relying on slightly different reasoning.\(^{67}\) Specifically, HHS contended that “where a state threatens to discontinue Medicaid coverage entirely, any waiver approval would promote coverage.”\(^{68}\) Judge Boasberg granted the plaintiffs’ motion for summary judgment, and once again vacated HHS’ approval of Kentucky’s Medicaid waiver.\(^{69}\)


\(^{64}\) “Subject to the full federal review process, CMS will support state efforts to test incentives that make participation in work or other community engagement a requirement for continued Medicaid eligibility or coverage for certain adult Medicaid beneficiaries in demonstration projects authorized under section 1115 of the Social Security Act (the Act).” Letter on Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries, from Brian Neale, Director, Ctrs. For Medicare & Medicaid Servs., to State Medicaid Directors (Jan. 11, 2018), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf.


\(^{66}\) Id. at 274.

\(^{67}\) Id. at 154.

\(^{68}\) Id. at 156.
Gresham, the lawsuit challenging Arkansas’ approved Medicaid waiver with work requirements, was also before Judge James Boasberg at the U.S. District Court of the District of Columbia. The plaintiffs alleged similar complaints as those in Stewart, and HHS conceded that “the administrative decision in this case shares the same problem as the one in Stewart I.” HHS argued the because Arkansas’ Medicaid waiver with work requirements was already operating, vacatur would be improper. Judge Boasberg disagreed:

Given the seriousness of the deficiencies — which, as this Court explains in a separate Opinion issued today [the Stewart II decision], the remand in Kentucky did not cure — and the absence of lasting harms to the Government relative to the significant ones suffered by Arkansans like Plaintiffs, the Court will vacate the Secretary's approval and remand for further proceedings.

Kentucky and Arkansas have filed notices of appeal to the D.C. Circuit, and final briefs are due August 1, 2019.

Shortly before the decisions in Stewart and Gresham were announced, four individual plaintiffs filed a lawsuit alleging similar complaints regarding New Hampshire’s work requirements. The plaintiffs allege that New Hampshire’s work requirements violate the Administrative Procedures Act and the Take Care Clause of the U.S. Constitution.

Implications: The appeals in Stewart and Gresham will provide direction on whether the Trump Administration’s support of Medicaid work requirements are a valid exercise of administrative authority absent Congressional action.

D. Preventive Services and Contraceptive Mandate Cases

The ACA Women’s Health Amendment requires that insurance providers cover preventive health services and screening for women, without cost-sharing responsibilities. The included preventive services are those set forth in the HRSA Guidelines, which include all FDA-approved “contraceptive methods, sterilization procedures, and patient education

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71 Id.
72 Id.
75 Id. at 41-43.
76 Id. at 43.
and counseling.” See 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). These requirements together are known as the “Contraceptive Mandate.”

A Final Rule was promulgated by government agencies providing an exemption for a “religious employer” or other eligible organizations if those eligible organizations met certain requirements. 78 Fed. Reg. 38,870, 39,871 (July 2, 2013). The Supreme Court weighed in on several challenges to the Contraceptive Mandate. See Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014) (holding the Mandate posed a substantial burden on the religious exercise of the plaintiff closely-held corporations and the burden was not the least restrictive means, violating the Religious Freedom Restoration Act); Wheaton College v. Burwell, 573 U.S. 958 (2014) (holding the plaintiff need not use the self-certification form prescribed by the government to access the accommodation); Zubik v. Burwell, 136 S. Ct. 1557 (2016) (per curiam) (remanding a case for the parties to consider an alternative approach accommodating both religious exercise and ensuring women’s access to coverage when non-profit employers claimed requirement to notify the government of objection so government can order insurer to provide the coverage (at no cost to employer) violated the RFRA).

After the President issued an order encouraging the relevant agencies to address conscience-based objections to the Mandate, the agencies issued new interim and then final rules relating to a Religious Exemptions and Moral Exemptions. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536, 57,536 (Nov. 15, 2018) (“Final Religious Exemption”); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018) (“Final Moral Exemption”). These Final Rules made changes to the previous exemption and accommodation framework, including:

1. Moral Exemption made exemption available to “additional entities,” including for-profit entities not publicly traded, that objected based on “moral convictions.”
2. Religious Exemption significantly broadened the scope of the religious exemption to include any non-profit or for-profit entity, whether closely held or publicly traded.
3. Both Exemptions expanded eligibility for the accommodations based on religious or moral convictions.
4. Both Exemptions removed the requirement for the self-certification process.
5. Both Exemptions removed the requirement to provide any notice of intent to take advantage of the exemption or accommodation, allowing entities with religious or moral objections to decide, without notice, not to provide contraceptive coverage to employees.

There have been several challenges to these Final Rules and, as of January 2019, the Rules have been enjoined nationwide.


Summary: Pennsylvania (later joined by New Jersey) challenged the Moral Exemption and Religious Exemption rules on several grounds and sought a preliminary injunction. The District Court previously held that the agencies issuing the Interim Final Rules failed to meet the various requirements of notice-and-comment rulemaking. See 5 U.S.C. §553. The District Court held that the plaintiffs would likely prevail on the claim that the invalid Interim Final Rules tainted the issuance of the Final Rules, rendering them invalid. The court also concluded that the Final Rules exceeded the scope of the agencies’ authority under the ACA. The court found that the Women’s Health Amendment sets out who is bound by the mandate by directing exactly who—all group health plans or individual/group health insurance issuers—“shall” provide coverage for “preventive care.” The agencies did not have authority to carve out, contrary to the express terms of the statute, categories of entities who are not required to provide preventative care coverage. The court held the ACA therefore prohibits the exemption of entities as set forth in the Final Rules. The court also held that the Religious Freedom Restoration Act did not require the broad Religious Exemption and grants the courts, not the agencies, the power to determine “whether generally applicable laws violate a person’s religious exercise.”

Accordingly, Judge Beetlesone issued a nationwide preliminary injunction of the Final Rules, finding the states would suffer irreparable harm, the states have a clear interest in “securing the health and well-being of women residents and limiting their costs for contraceptive services, and there is a public interest in maintaining the status quo under the Mandate. The court stated: “Fundamentally, given the harm to the states should the final rules be enforced — numerous citizens losing contraceptive coverage, resulting in ‘significant, direct and proprietary harm’ to the states in the form of increased use of state-funded contraceptive services, as well as increased costs associated with unintended pregnancies —a nationwide injunction is required to ensure complete relief to the states.”

Other Contraceptive Mandate Cases:


Massachusetts v. United States Dep’t of Health & Human Servs., No. 18-1514, 2019 WL 1950427 (1st Cir. May 2, 2019) (remanding after holding Massachusetts’ substantive challenges

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78 The government recently argued that Oregon should not be included in the scope of the injunction because the judge in Pennsylvania v. Trump already issued a nationwide injunction so there is no irreparable harm.
to the Interim Final Rules have not been mooted by the Final Rules but its procedural challenges have been mooted; and the state has standing to challenge the substance of the rule by demonstrating a sufficiently imminent fiscal injury).

**Implications:** The final outcome of these cases will determine the scope of the Contraceptive Mandate, as well as the agencies’ authority to make exceptions to that scope.

**II. Medicare Advantage Risk Adjustment Cases**

Under Medicare Advantage (“MA”), the Center for Medicare and Medicaid Services (“CMS”) contracts with private insurers known as Medicare Advantage Organizations (“MAOs”) to offer Medicare coverage to eligible individuals as an alternative to traditional Medicare. CMS pays the MAOs monthly premiums for each MA member and the MAO bears the risk of the actual costs of medical care.

1. **Risk Adjustment**

MA premiums are adjusted, in part, based on the “risk” of a member. The higher the risk, the higher the premium payment will be for that member. Risk is based on a number of factors such as age, sex, and diagnoses of the member. Member diagnosis conditions collected and submitted by the MA insurer to CMS support the risk score of a member that is used to determine the proper premium payment (Hierarchical Condition Category (“HCC”) model). The base rates for each risk category are based on average expenditure for an average beneficiary under traditional Medicare.

2. **RADV Audits**

Beginning with payment year 2007, CMS began conducting Risk Adjustment Data Validation (“RADV”) audits. RADV audits consist of CMS choosing a sample of members under a particular MA-CMS contract and reviewing the medical record documentation to substantiate the conditions submitted to CMS. CMS recovered a substantial amount in overpayments for payment year 2007 for MA member risk scores it found to be unsubstantiated by the medical records (over $10 million), and is still completing audits for payment years 2011-2013 (30 plans audited). CMS just recently began a new round of audits for payment year 2014, which expanded to many more MA plans and contracts.

3. **RADV Audit Formula Proposed Changes**

For the 2007 audits, only those payments for audited sample plan member risk scores found unsubstantiated were deemed overpayments. In 2012, CMS promulgated a RADV audit formula that extrapolated an error rate for each audited MA plan based on the results of the audit of the sample of plan members. This formula included a fee-for-service (“FFS”) adjuster that accounted

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for the effect of erroneous diagnosis codes in the traditional Medicare data, i.e. the FFS adjuster would determine a permissible level of payment error and limit RADV audit recovery to errors above that level. CMS used this formula in its 2011-2013 audits but has not finalized the audit results or recovered any overpayments.

CMS has now issued a proposed rule to revise the MA RADV audit formula to apply extrapolation to the audits for 2011 forward and to exclude the FFS adjuster. CMS states that it conducted a study on October 26, 2018, analyzing the impact of errors in FFS claims that shows diagnosis errors in FFS claims data does not lead to systematic payment error in the MA program. According to CMS, a review of medical records for more than 8,000 claims and other additional data showed that the level of inaccuracy can be 40% or higher. But CMS also concluded that the beneficiary level error associated with each HCC was much lower, with a median error rate of 2%. CMS requested a 120-day extension on the comment period for the proposed rule, until April 30, 2019.

There are disputes on both sides of the aisle relating to risk adjustments, including challenges to RADV audit methodology and to MA insurers’ obligations as to the submission and support of risk adjustment data.

A. 2014 Overpayment Rule Case


Status: Summary Judgment granted against Defendants, vacating 2014 Overpayment Rule. Appeal to the D.C. Circuit Court is stayed pending resolution of Rule 60(b) Motion for Reconsideration at the District Court. The District Court Rule 60(b) briefing schedule is stayed until October 26, 2018 FFS Adjuster Study data is released.

Summary: UnitedHealthcare Insurance Company and other United entities brought suit against the Secretary of DHHS, CMS, and the United States in relation to the 2014 Overpayment Rule, which implements the Affordable Care Act requirement that MA Organizations report and return any overpayments that they identify. Under the ACA, an overpayment must be reported and returned within 60 days after identification. Failure to return an overpayment within 60 days of identification can lead to “reverse” false claims act (“FCA”) liability, i.e., for avoiding an obligation to the Government. Under the 2014 Overpayment Rule, any submitted diagnosis code not adequately documented by in the medical records would result in an overpayment. Further, “[t]he MA organization has identified an overpayment when the MA organization has determined,

80 See 83 Fed. Reg. 54,982, 54,984, 55,037-55,041 (proposed Nov. 1, 2018) (to be codified at §§ 422.300, 422.310(e), and 422.311(a)) at https://www.govinfo.gov/content/pkg/FR-2018-11-01/pdf/2018-23599.pdf
82 See id. at 29921.
or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.” 42 C.F.R. § 422.326(c) (emphasis added).

The plaintiffs alleged in Azar:

(1) The 2014 Overpayment Rule does not ensure the statutory requirement of “actuarial equivalence” between CMS’s own costs and what CMS pays MA insurers to provide the same coverage, nor does it meet the “same methodology” requirement.

(2) The “negligence” standard of liability under the 2014 Overpayment Rule constitutes an unlawful departure from standard of liability under the FCA.

On cross-motions for summary judgment, the court ruled in favor of the plaintiffs, vacating the 2014 Overpayment Rule as arbitrary and capricious in light of its failure to meet “actuarial equivalence” and “same methodology” requirements for CMS MA payments. See 42 U.S.C. § 1395w-23(a)(1)(C)(i) and (b)(4)(D).

The court concluded that actuarial equivalence requires that the present values of two modes of payment are equal under a given set of actuarial assumptions—i.e., they must have the same set of actuarial assumptions—and different assumptions would necessarily result in non-equivalent results. Both Medicare and MA are set annually based on costs from unaudited traditional Medicare records submitted. Under traditional Medicare, the diagnosis codes used to determine MA payment rates are irrelevant because doctors bill and are paid based on the procedure, not the diagnosis code. Thus, the court concluded that the 2014 Overpayment Rule systematically devalues payments to MA insurers by measuring “overpayments” based on diagnosis information in audited patient records, thereby creating an actuarial difference. In other words, using unaudited CMS data to set the MA payment rates, and then using audited data to define overpayments, leads to lower payments for MA insurers for comparable patients.

The court found the same is true under the “same methodology” requirements. CMS’s methodology for overpayments involves a reconciliation based only on audited diagnosis codes of

83 CMS is required to base its average risk factor (that determines MA payment rates), on the “same methodology” expected to be applied in making payments to MA organizations. 42 U.S.C. § 1395w-23(b)(4)(D). As to actuarial equivalence:

The Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

MA patients, in contrast to the unverified diagnosis codes for traditional Medicare patients used to set payment rates.

The court noted that CMS recognized the actuarial equivalence issue in its RADV audit methodology (prior to the new proposed rule). Under RADV audits, an overpayment exists only when the error rate for the MA contract is greater than the CMS error rate (application of FFS adjuster). CMS’s rationale for applying the FFS adjuster to RADV audits is to “account for the fact that the documentation standard used in RADV audits to determine a contracts payment error (medical records) is different from the documentation standard used to develop the [MA] risk-adjustment model (FFS claims).” The 2014 Overpayment Rule, however, does not account for this issue.

The court held that CMS was arbitrary and capricious in adopting the 2014 Overpayment Rule without explaining a legitimate reason for abandoning its statutory mandate.

The court also held that the 2014 Overpayment Rule improperly allows FCA liability for negligent conduct. The ACA requires overpayment repayment within 60 days of “identifying” an overpayment. 42 U.S.C. § 1320a-7k(d)(2). The 2014 Overpayment Rule states: “The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.” 42 C.F.R. § 422.326(c) (emphasis added). CMS explained in 2014 Overpayment Rule that “at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.”

But the FCA requires submission of erroneous claims to the government “knowingly.” Knowingly is defined as actual knowledge, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. §3279(b)(1)(A). The court concluded that the CMS definition of “identified” is distinctly different and more burdensome than the one proposed.

Accordingly, the court struck down the 2014 Overpayment Rule. The government sought reconsideration from the court and also filed an appeal to the D.C. Circuit Court. The D.C. Circuit appeal is stayed pending the District Court’s determination of the reconsideration motion. The District Court briefing schedule for the motion for reconsideration is stayed pending the release of the CMS study addressing the FFS adjuster.

**Implications:**

1. Despite this holding, CMS has proposed its new rule for RADV audits that does not apply the FFS adjuster, relying on its FFS adjuster study as the basis for the
exclusion. CMS has said that it plans to extrapolate the results of its RADV audits without accounting for the FFS adjuster. If carried out (for the 2011-2013 and new 2014 RADV audits), CMS expects $1 billion in savings from overpayment recovery and at least $381 million each subsequent year.

2. The ultimate outcome of the litigation will impact whether CMS can permissibly recover amounts as a result of audits without using the FFS adjuster in its RADV methodology.

3. The outcome will also likely have a significant impact on the Risk Adjustment submission FCA cases as discussed in Section B below – these cases also relate to when MA entities are liable for overpayments and FCA liability in relation to risk adjustment submissions and payments.

B. Risk Adjustment Submission Cases – False Claims Act

_Swoben v. United Healthcare Ins. Co., 848 F.3d 1161 (9th Cir. Dec. 16, 2016), remanded to district court as Swoben v. SCAN Health Plan, No. 2:09-cv-05013 (C.D. Cal.)_

**Status:** Voluntarily dismissed by the government in October 2017 after defendants’ motion to dismiss granted.

**Summary:** Qui tam action filed in 2009 against multiple defendants alleging false attestations of risk adjustment data in violation of the FCA, and later amended to add additional defendants. Some defendants settled (SCAN defendants). The district court dismissed the complaint for a failure to plead with particularity and found any amendment would be futile. The Ninth Circuit, however, reversed, holding that the deliberate avoidance of identifying certain erroneous coding is a “cognizable legal theory” under the FCA because MA Plans are obligated by Medicare regulations to undertake “due diligence” to ensure the accuracy of diagnostic codes, and FCA liability can be established by a defendant’s deliberate ignorance. See _United States v. United Healthcare Ins. Co._, 848 F.3d 1161, 1172-79 (9th Cir. 2016).

On remand, the government filed a complaint in partial intervention against the United defendants only, asserting FCA and reverse FCA claims, unjust enrichment and payment by mistake. _Swoben v. SCAN Health Plan, No. 2:09-cv-05013 (C.D. Cal.)_ This was the government’s first intervention in a Medicare FCA suit. On a motion to dismiss, defendants argued the government’s complaint should be dismissed because, among other issues, it failed to allege that the individuals who signed the attestations “knew” they were false or that the attestations were “material” to the government’s decision to pay under _Escobar_. Defendants also sought to dismiss the government’s “reverse false claims act” claim, arguing it had been waived (by Swoben).

The court held that _Escobar_’s strict “knowingly” scienter requirement was “rigorous” and “strictly enforced,” and the government’s complaint failed to identify the particular corporate officers who signed the attestations or allege that those individuals knew or should have known that the attestations were false. The court also concluded that the complaint failed to meet the heightened
“materiality” standard under Escobar because the government made merely a conclusory statement that the conduct was material, without alleging that CMS would have refused to make the risk adjustment payments to defendants had it known the facts alleged. The court also held that the government could not revive the “reverse false claims act” theories that were dismissed and not appealed to the Ninth Circuit before the government intervened.

While the FCA claims were dismissed with leave to amend, the government opted not to amend, instead filing a notice of voluntary dismissal, without prejudice, in October 2017.


Status: Case proceeding after summary judgment motion practice concluded in March 2019.

Summary: Qui tam action, in which government intervened, claiming (as in Swoben) the defendant MAOs conducted one-way chart reviews, identifying only additional diagnosis codes to submit to CMS and ignoring unsupported diagnosis codes to delete, in violation of FCA. The complaint alleged that the defendants knew about the unsupported code issue because of audit error rates (RADV audits) that put them on notice. The government alleged, as in Swoben, that defendants’ attestations about the accuracy of their risk adjustment submissions were false under the FCA. Unlike Swoben, the government also alleged reverse FCA claims for failing to return identified overpayments based on the allegedly invalid diagnostic data the defendants submitted and failed to delete.

On February 12, 2018, the district court dismissed the government’s claims based on allegedly false “attestations” of risk adjustment data, finding these allegations failed to meet the Escobar materiality standard because the government failed to allege that its payments would have changed had it known the attestations were false. The regulatory requirement to attest that the data is accurate, complete, and truthful based on “best knowledge, information, and belief” is not enough, the government must allege the attestations have a direct impact on the payments. Thus, like in Swoben, the court held the government’s FCA claims based on attestations fails.

The court, however, allowed the reverse FCA claims—based on actual submission of allegedly invalid data—to go forward. The court concluded the government sufficiently pleaded the claim that, because the defendants’ failed to delete invalid diagnoses, they failed to return to Medicare the overpayments received based on invalid diagnosis codes.

On March 28, 2019, the court denied the government’s motion for partial summary judgment as to the defendants’ disputed obligation to delete unsupported diagnosis codes. The court held a question of fact remained on whether such obligation exists in light of the actuarial equivalence and same methodology mandates of the Medicare Act. See 42 U.S.C. §§ 1395w-23(b)(4) (same methodology required), (a)(1)(C)(i) (actuarial equivalence required). The court found the Azar decision persuasive in deciding the federal regulations do not unambiguously support the
government’s proposed rule. The court also concluded the MA contracts do not unambiguously require the deletion of unsubstantiated diagnosis codes. Thus, a question of fact remains on this obligation.

The court, however, granted the government’s motion to strike the defendants’ affirmative equitable defenses because judicially created doctrine cannot bar the government from recovering money paid in the absence of statutory appropriation. The court also dismissed, without prejudice, the defendants’ counterclaim similar to the allegations in the Azar case—a lack of actuarial equivalence and a lack of the same methodology. The defendants alleged CMS calculates MA payments based on both supported and unsupported codes (no auditing) so if MA plans are required to delete all unsupported codes, CMS would get a windfall and MA Plan would be underpaid. See Case No. 16-08697, Doc. 223 (C.D. Cal.). The court found it lacked jurisdiction over this claim because United failed to plead any applicable waiver of sovereign immunity and the court declined to sever and transfer the claims for lack of jurisdiction by the Federal Court of Claims because of a parallel action (Azar).

United States ex rel. Silingo v. Mobile Medical Examination Services, Inc., Case No. 8:13-cv-1348-FMO-JC (remanded by Case No. 16-56400, 904 F.3d 667 (9th Cir. July 9, 2018))

Status: After remand from the Ninth Circuit, case is proceeding with Fourth Amended Complaint filed May 16, 2019.

Summary: Qui Tam action alleging Medicare Advantage organizations retained MedXM to fraudulently increase risk scores by fabricating diagnoses and/or using diagnosis not collected properly (e.g. face to face visit by a doctor). The government declined to intervene. The district court dismissed the claims against the MAOs with prejudice on the ground that the allegations “remain undifferentiated.”

The Ninth Circuit reversed in part, concluding that when all the defendants are essentially alleged to have engaged in the same conduct—contracting with MedXM and passing on the inflated diagnosis codes—group allegations are sufficient to meet heightened fraud pleading standard (wheel conspiracy-like fraud versus chain conspiracy). The court also declined to dismiss on alternative grounds. First, the court held the plaintiff did not have to allege the inner workings of the data submission process—it is enough that the plaintiff alleged that each MAO contracted with MedXM and submitted the MedXM data, and the plaintiff detailed the MedXM inflated coding scheme. Second, the court also held the knowledge allegations were sufficient under Rule 8 because there were allegations establishing the MAOs submitted false claims and certifications and used false records with actual knowledge, reckless disregard, or deliberate ignorance of their

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84 The government pointed to, for example, the RADV regulations requiring submission of records to validate risk adjustment data. 42 C.F.R. § 422.310(e).
falsity. The court declined to revive the reverse FCA claim because the plaintiff failed to defend it in response to the motion to dismiss.

After remand, the plaintiff filed a fourth amended complaint on May 16, 2019, adding some additional defendants and removing others.

**Other Risk Adjustment FCA Actions**

- **Valdez v. Aveta, Inc.**, Case No. 3:15-cv-01140-CCC (D. Puerto Rico) (claiming submission of unsupported codes and failure to delete invalid codes; uses provider risk contracts to bolster claims of incentive to inflate; DOJ declined to intervene; Pretrial conference on 5/22/19 and readying for trial if not settled)

- **United States v. UnitedHealthcare Ins. Co.**, No. 15-CV-7137, 2018 WL 2933674, at *3 (N.D. Ill. June 12, 2018) (dismissing complaint by MA member alleging insurer conducted in-home exams not medically necessary to collect risk adjustment data – CMS approves the use of such in-home exams for care and RA data collection)


- **United States v. Janke**, No. 2:09-cv-14044-KMM (S.D. Fla.) (applying sampling and alleging that the MAO falsely submitted risk adjustment data; settled in 2010 for $22.6 million and assignment of receiviorship funds)

- **United States ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.**, No. 3:14-CV-00118-M, 2016 WL 5661644, at *1 (N.D. Tex. Sept. 30, 2016) (including Humana, Altegra Health, Tufts plans and Censeo Health (who provided the RA services); claims against Humana and Tufts dismissed on motion to dismiss for failure to meet Rule 9(b) requirements; settled October 2017)

**Implications/Take Aways of Risk Adjustment FCA Actions:**

- It remains to be seen what the courts will ultimately decide about whether MAOs have an obligation to delete invalid diagnosis codes and whether the failure to do so can result in FCA or reverse FCA liability.

- The ultimate outcome in *Azar* will likely impact how these cases play out, particularly given the *Poehling* court’s recognition of *Azar* as persuasive as to the question of whether an obligation to delete unsupported diagnosis codes exists in light of the actuarial equivalence and same methodology mandates of the Medicare Act.

- Under the FCA, courts appear to be taking the *Escobar* requirements seriously – materiality and knowledge.
• While the courts have prevented FCA claims, however, reverse FCA claims seem to be getting around some of the stringent Escobar requirements.
• District Courts are taking a close look at the Rule 8 and 9 pleading standards but at least the Ninth Circuit seems to potentially have a less stringent view.

III. Mental Health and Substance Use Disorder Coverage Cases

**Status:** The District Court is considering appropriate remedies; motions were due May 3, 2019.85 United Behavioral Health filed a motion challenging the certification of the class.86 An appeal the Ninth Circuit is expected.

**Summary:** The case was brought in the U.S. District Court of the Northern District of California. It is a class action, and all of the “class members’ health benefit plans grant discretion to United Behavioral Health (“UBH”), as the claims administrator, to interpret plan terms, limitations and exclusions in determining whether a requested service is covered.”87 Each of the named plaintiffs requested coverage for residential treatment services for mental illness or substance use disorder, and the requests were denied by UBH in reliance on its Level of Care Guidelines and Coverage Determination Guidelines. While the case addresses coverage of mental health and substance use disorder services, the plaintiffs amended the complaint to remove the Mental Health Parity and Equity Act claims earlier in the pleading process. The plaintiffs sought five types of relief: (1) declaration that the internal guidelines were developed in violation of fiduciary duties; (2) permanent injunction ordering that UBH stop using the guidelines and adopt or develop guidelines consistent with generally accepted standards and state law; (3) declaration that the denials of coverage were improper; (4) a remand to the administrator to reprocess all class member claims using the new guidelines; and (5) additional equitable relief.

On March 5, 2019, the federal magistrate held that UBH breached its fiduciary duties under ERISA in its functional role as a claims administrator because the Guidelines were not consistent with the generally accepted standards of care. The Guidelines set a higher bar for plaintiffs to reach in order to receive coverage for the requested services. The Court focused on whether UBH provided claims administration services consistently with the terms of the group health plans. The Court focused on what it believed to be UBH’s excessive emphasis on addressing acute symptoms rather than the systemic treatment of the participants’ underlying conditions. The Court also concluded that UBH’s expert witnesses had serious credibility problems, describing their testimony as “evasive” and “deceptive” when the witnesses tried to reconcile the UBH Guidelines to the

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generally accepted standards of care. Finally, the Court concluded that the plaintiffs met the three requirements of a successful breach of fiduciary claim under ERISA.

**Implications:** If the decision is not otherwise overturned, the clearest implication is for carrier-developed level of care guidelines for behavioral health benefit that deviate at all from medical societies’, CMS’, or state-mandated guidelines. In addition to implicating that courts can determine “generally accepted medical standards” for a range of conditions over a multi-year period, the decision also purports to set forth those standards and give them the authority of case law.\(^{88}\)

**Other applicable cases\(^{89}\):**


IV. **ERISA Cases**

A. **Cross-Plan Offseting**

*Peterson on behalf of E v. UnitedHealth Grp. Inc.*, 913 F.3d 769 (8th Cir. Jan. 15, 2019) and *Riverview Health Institute v. UnitedHealth Group, Inc. et al*, Case No. 15-cv-03064-PJS-BRT (D. Minn) *(rehearing and rehearing en banc denied (Mar 01, 2019))*\(^{90}\)

**Status:** Cases proceeding in District Court after immediate appeal of summary judgment to the Eighth Circuit.

**Summary:** Consolidated class actions where plaintiffs (as assignees or ERISA authorized representatives) brought ERISA claims challenging plan administrators’ practice of cross-plan offsetting—offsetting overpayments made to providers with payments from different plans—as unauthorized under the plan documents. The providers are often out of network (“OON”) and the offsetting may occur in relation to self-funded and fully insured ERISA plans.

The District Court granted summary judgment in favor of plaintiffs on the issue of the defendants’ authority under the plan documents to engage in cross-plan offsetting. The court concluded that all of the plans allow for same-plan offsetting, but none explicitly authorize cross-plan offsetting, and the general provisions allowing administrators to pay benefits and to use discretion in interpreting and administering the plan are not enough. Thus, the interpretation of the plan documents was not reasonable under the Eight Circuit’s factors in *Finley v. Special Agent Mutual*

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89 See also Legal Cases, PARITYTRACK (last visited May 23, 2019), https://www.paritytrack.org/resources/legal-cases/?status=pending.

90 Considered together on appeal to the Eighth Circuit.
Benefit Association, Inc., 957 F.2d 617, 621 (8th Cir. 1992). The district court certified its order for immediate appeal.

The Ninth Circuit affirmed as to Peterson. The court found the defendants abused their discretion in interpreting the plans to allow for cross-plan offsetting because, as the district court concluded, nothing in the plan language explicitly authorized such offsetting. Additionally, the court concluded the practice of cross-plan offsetting is in tension with ERISA’s fiduciary requirements but expressly declined to decide whether the practice necessarily violates ERISA.

While administrators like United may happen to be fiduciaries of multiple plans, nevertheless “each plan is a separate entity” and a fiduciary's duties run separately to each plan. Standard Ins. Co. v. Saklad, 127 F.3d 1179, 1181 (9th Cir. 1997).

Cross-plan offsetting is in tension with this fiduciary duty because it arguably amounts to failing to pay a benefit owed to a beneficiary under one plan in order to recover money for the benefit of another plan. While this benefits the latter plan, it may not benefit the former. It also may constitute a transfer of money from one plan to another in violation of ERISA’s “exclusive purpose” requirement. 29 U.S.C. § 1104(a)(1).

The court went on the conclude that “[r]egardless of whether cross-plan offsetting necessarily violates ERISA, it is questionable at the very least. Considering this, alongside the fact that there is no plan language—only broad, generic grants of administrative authority—that would authorize the practice, leads us to conclude that United's interpretation is not reasonable.”

The court denied a petition for en banc rehearing and also for rehearing by panel on February 5, 2019. Defendants’ motion to stay the mandate pending appeal to U.S. Supreme Court was denied on March 15, 2019.

Post appeal, on April 12, 2019, the District Court Magistrate Judge denied the plaintiffs’ motion for leave in Peterson to file a second amended complaint to add a claim for fiduciary breach under ERISA § 1132(a)(2). The Magistrate found undue delay (declining to address the argument that plaintiffs previously disavowed the claim) because there was no justification. The plaintiffs had made numerous factual allegations regarding breach of fiduciary duty since early in the case and

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91 The Ninth Circuit held it lacked jurisdiction to review the order regarding Riverview because of standing issues.
92 The U.S. Department of Labor (“DOL”) filed an amicus brief in which took the position that cross-plan offsetting violated ERISA’s prohibited transaction and fiduciary rules, at least where overpayments from a plan insured by the administrator are recovered from amounts owed by a separate self-insured plan. The DOL reasoned that cross-plan offsetting imposed on “innocent participants a financial risk and potential harm in order to recoup an alleged, unrelated overpayment for another plan.” The DOL concluded that the insurer received an improper benefit, because recoveries out of the self-insured plans’ assets flowed back to plans for which the insurer was financially responsible. The DOL also noted, however, that such offsetting does not raise the same risks when done with in-network providers who often have their own contract that removes participants’ and plans’ interests from the dispute.
the defendants would suffer prejudice if an amendment were permitted at this stage. Plaintiffs had indicated during the case that if they won on these threshold issues, the case should then proceed directly to class certification (in Peterson) and then damages. Adding new claims at this late stage would “fundamentally alter the nature of this case and result in undue resources expended by Defendants in litigating this case.” On April 26, the plaintiffs filed objections to the Magistrate Judge’s order, which is currently pending before the court.

**Implications:** The future of cross-plan offsetting is uncertain.

- Under the Eight Circuit opinion, the practice might be permissible under certain circumstances but still raises considerations for the fiduciaries and plan sponsors.
- For now, if you want to use cross-plan offsetting, make sure it is expressly authorized in the plan documents.
- Employer plan sponsors (fiduciaries) should determine whether their administrators are using cross-plan offsetting and, if so, how it is used (i.e. fully insured versus self-funded plans).

**Other Cross-Plan Offsetting Cases:**


**B. Member Drug Charge Class Actions**

Class action cases by plan members relating to allegations of overcharging for Part D drug cost-sharing amounts due to “clawbacks” the insurers and/or PBMs receive. Several insurers and PBMs, including UnitedHealth Group, Cigna, Humana, CVS Health Corp., and Walgreens have been subject to these suits. The first defendants to defeat one of these suits was UnitedHealth Group. See *In re: UnitedHealth Grp. PBM Litig.*, 2017 WL 6512222 (D. Minn. Dec. 19, 2017).

In that case, the court dismissed without prejudice the plaintiff’s claim under ERISA § 502(a)(1)(B) to recover benefits or enforce or clarify rights under the plan because the plaintiff had failed to exhaust administrative remedies. The court also dismissed without prejudice the plaintiff’s ERISA claims for breach of fiduciary duty and prohibited transaction, concluding the plaintiff failed to adequately plead any defendant acted as a plan fiduciary when engaging in the conduct plaintiff alleged. The court also dismissed the plaintiff’s RICO claims without prejudice, concluding that the plaintiff failed adequately to plead the existence of a RICO enterprise.

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93 Plaintiffs originally asserted a breach of fiduciary claim in the *Riverview* case but then voluntarily dismissed that claim.
The plaintiff then filed suit in the Southern District of New York, asserting similar (and some same) claims.

_Mohr-Lercara v. Oxford Health Ins., Inc., S.D.N.Y., No. 7:18-cv-01427 (complaint filed 2/16/18)_

**Status:** Case is proceeding after the defendants’ motion to dismiss was granted in part and denied in part.

**Summary:** Class action suit in which the plaintiff claims the defendants breached their fiduciary duties under ERISA when they executed an alleged overcharging scheme relating to drug charges, and alleging a racketeering scheme under RICO to fraudulently overcharge plan beneficiaries for prescription drugs.

On March 28, 2019, the district court granted in part and denied in part the defendants’ motion to dismiss. The court dismissed the substantive RICO claim against one defendant but not another, and dismissed the RICO conspiracy claim as to one defendant but not as to the two others. The court also concluded that the plaintiff is collaterally estopped, because of the _In re: UnitedHealth Grp. PBM Litigation_, from rearguing that she need not exhaust administrative remedies, or that exhausting administrative remedies by appealing the denial of her grievance would be futile. But the court found unclear in the complaint whether the plaintiff had failed to exhaust administrative remedies so denied dismissal on that ground.

As to ERISA liability, the court held that the plaintiffs were not precluded from arguing the defendants were plan fiduciaries, except collateral estoppel bars plaintiff from rearguing that defendants acted as plan fiduciaries when they required pharmacies to (i) remit overcharges to defendants, or (ii) misrepresent patients' proper cost-sharing amounts. Collateral estoppel also bars plaintiff from rearguing that defendants acted as plan fiduciaries when they prevented pharmacies from disclosing to patients (i) proper cost-sharing amounts, (ii) the existence of the overcharges, (iii) how pharmacies charged patients for covered prescription drugs, or (iv) that patients’ covered prescription drugs could cost less if purchased without using insurance.

The court found the plaintiff had adequately pleaded that defendants acted as fiduciaries by setting and collecting their own compensation in the form of the clawback. The court also found that the plaintiff adequately alleged defendants exercised fiduciary authority or control over plan assets.

**Implications:** Inflated drug prices are a hot issue right now, not only in litigation. The outcome of this and other litigation could have a substantial impact on the relationships between plans, manufacturers, PBMs and others.
C. Other Notable ERISA Cases

  o Challenging health-plan fiduciary oversight and reasonableness of fees similar to actions against fiduciaries of defined-contribution retirement plans.
  o While main issue is whether these plans were improperly designated as governmental entity plans, which are exempt from ERISA, the key issue for health-plan fiduciaries is whether the fiduciary retained a costly, affiliated entity as a third-party administrator for its health plan and failed to ensure that participants paid only ‘reasonable’ fees for services, co-insurance and deductibles.
  o *Status:* Motion to dismiss for failure to state a claim is pending

- **Associated Health Plans under ERISA** – *New York v. U.S. Dep’t of Labor*, Case No. 18-1747 (D.D.C. Mar., 28 2019) (striking down Final Rule adopting a new definition of “employer” under ERISA allowing Associated Health Plans to qualify as group health plans and employers under ERISA, thereby avoiding many ACA requirements)

- **Anti-Assignment**
  o *California Spine & Neurosurgery Institute v. Blue Cross of California*, 358 F. Supp. 3d 949 (N.D. Cal. Jan. 7, 2019) (holding anti-assignment defense is a litigation defense so not waived when not asserted as reason for denial during administrative appeal)
V. **Air Ambulance Services Cases**

Air ambulance services can cost tens of thousands of dollars. Some insurers refuse to pay the full amount, leading to balance-billing the members. There have been multiple lawsuits over whether the federal Airline Deregulation Act of 1978 (ADA) preempts state laws that establish air ambulance reimbursement rates. Courts have predominantly found the ADA applies to air ambulance services as “air carriers” and preempts such state laws. The ADA, meant to deregulate and apply free market principles to the commercial aviation sector, expressly prohibits any government controls of pricing and expressly prohibiting states from enacting or enforcing “any law, rules, regulation, standard or other provision having the force and effect of law related to a price, route, or service of an air carrier.” Proposed legislation at the federal level (S.471), that would preserve states' authority to regulate air ambulance billing, remains pending.


*Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751 (4th Cir. Dec. 7, 2018) (enjoining West Virginia laws limiting reimbursement rates of air ambulance companies for worker’s compensation claims and state employee claims, concluding such laws are preempted by the ADA)

*Medical Mutual of Ohio v. Air Evacs EMS, Inc.*, 341 F. Supp. 3d 771 (N.D. Ohio Sept. 17, 2018) (finding some claims of air ambulance carrier against insurer for additional payment of claims not preempted by ADA and some raised a question of fact)

*Stout v. Med-Trans Corp.*, 313 F. Supp. 3d 1289 (N.D. Fla. May 2, 2018) (holding proposed class action patient claims for excessive air ambulance charges preempted by the ADA and ADA does not violate constitutional rights)

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94 The McCarran-Ferguson Act was enacted to ensure states have the preeminent role in the regulation of the insurance industry. Its reverse preemption provision states: “No Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, or which imposes a fee or tax upon such business, unless such Act specifically relates to the business of insurance. . . .” 15 U.S.C. § 1012(b).
Responding to Government Audits: Specific Tips That Will Produce Better Outcomes for Your Client

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June 19, 2019

AGENDA

• Overview of Medica and Bright Health
• General Audit Preparedness
• Examples of Reviews
  – Affordable Care Act (Qualified Health Plans)
  – Medicare Advantage (MA)
  – Medicaid
  – Office Of Legislative Auditor (OLA)
• Basic Preparation
• Organizing the Audit
• How and When to Work with the Legal Team
• Lessons Learned
Founded in 2015
Vision: Collaborating with Care Partners to make health care simpler, personal, and more affordable.
Mission: Making Healthcare Right. Together
$440 M capital raise
Offers individual ACA and Medicare Advantage products
Headquartered in Minneapolis, MN

MEDICA OVERVIEW – Service Area

Regional non-profit health plan based in Minnesota
- Medicare, Medicaid, Individual (ACA) and Commercial
- ~1,500 employees in Minnetonka, Omaha, Fargo, Duluth, and St. Cloud

Individual coverage
- All states except South Dakota
- Entered Oklahoma and Kansas City, MO markets in 2019

Commercial coverage in MN, ND, WI, and SD

Medicare coverage in MN, WI, ND, SD, IA, and NE
- Medicare Advantage (MA) and Medicare Supplement plans in MN
- Cost Plans in MN, ND, SD, WI, select counties in IA and NE

Medicaid -- Medica serves aged and disabled Minnesotans eligible for Medicaid and Medicare

Mission
To be the trusted health plan of choice for customers, members, partners and our employees.

Vision
To be trusted in the community for our unwavering commitment to high-quality, affordable health care.
General Audit Preparedness

- Know your regulators and maintain strong relationships
  - Monitor enforcement actions, audit schedules, and audit protocol evolution
  - Maintain strong in-person relationships with regulators
- Champion strong organizational culture of compliance
- Set clear organizational expectations
- Establish clear internal and external lines of communication
- Tie employee performance review and compensation to organizational compliance objectives
- Practice Practice Practice
### Examples of External Audits

- ACA federal reviews
  - Conducted by CMS’ Center for Consumer Information and Insurance Oversight (CCIIO)
    - CCIIO oversees the implementation of the provisions related to private health insurance
    - CCIIO review types:
      - Medical Loss Ratio reviews
      - Federal Market Conduct Examinations (even in direct enforcement States)
      - Federally Facilitated Exchange (FFE) Compliance Reviews (so far “good faith”)
        - Standard, limited and targeted reviews
      - Advanced Payments of the Premium Tax Credit review (APTC)
- More details: [https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams_Audits_Reviews_Issuer_Resources-.html](https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams_Audits_Reviews_Issuer_Resources-.html)

### CCIIO - FFE Compliance Reviews

- Reviews the requirements for QHP certification and other FFE operational standards
- Comprehensive document requests, followed by Web-Ex interviews:
- Look back - current benefit year (annual certification and Open Enrollment period)
- Policy and Procedures
  - Delegated Entity Agreements
    - Copies of contracts, including agent/broker agreements
    - Delegated oversight process
  - Affiliated Agents/Brokers
    - Listing of NPNs
    - Date first policy application/sold
- Provider Directories and URLs
## CCIIO – FFE Compliance reviews (continued)

- Essential Community Providers Listing
  - Contract offers and Template agreements
- Prescription Drug Formulary and URL
- HICS Casework notes and resolution letters (review cases for timeliness)
- Enrollment Records
  - Welcome packets
  - Invoices
  - Notices
- Compliance, Privacy and Security
- Examples of regulatory and operational areas that will be reviewed –
  - see Key Priorities for FFE Compliance Reviews (CMS link previous slide)
- Requests for Corrective Action Plans

## Market Conduct Exams

Market Conduct Exams

- **Triggers:** complaints data/trends, Market Conduct Annual Statement (MCAS), market analysis, identification of unusual circumstances
- **Scope** will vary depending on agency audit priorities and reported issues with company
  - Targeted vs. comprehensive
  - Onsite vs. desktop
  - Single state vs. multi-state cooperative exam
- Standard market conduct exam areas:
  1. company operations/management;
  2. complaint handling;
  3. marketing and sales;
  4. producer licensing;
  5. policyholder service;
  6. underwriting; and
  7. claims
Market Conduct Exams

- Evolving examination areas/trends
  - Mental Health Parity exams
  - Cyber Security Issues
  - Requests for Disclosure of Internal Audits & Confidential Information
  - Use of Outsourced Examiners
- Market Conduct Annual Statement
  - Annual collection of claims, appeals/grievance, and enrollment/eligibility data
  - PY2017 was the first reporting year.
  - Results will be closely tied to selection of companies for exams.

Market Conduct Exams – Most Frequent Violations

- Failure to timely acknowledge, pay, investigate, or deny claims
- Failure to provide required claims & underwriting disclosures
- Use of unfiled/unapproved or noncompliant policy forms
- Improper documentation of underwriting and claim files
- Failure to adhere to required claims grievance and appeal processes, including timeframes and disclosures
- Failure to respond to regulatory requests for information
- Failure to use licensed/appointed producer and follow appointment requirements and maintain documentation
- Noncompliant claim denial notices
- Failure to adhere to replacement requirements
- Failure to pay claims properly per policy provisions
CMS Medicare Advantage

- CMS Program Audit
  - ODAG (Part D)
    - Coverage Determinations, Organization Determinations, Appeals and Grievances
  - Formulary Administration (Part D)
  - ODAG (Part C)
    - Organization Determinations, Appeals and Grievances
  - Special Needs Plans – Model of Care
  - Compliance Program Effectiveness (CPE)
- Financial Activity Audits
- Risk Adjustment Data Validation Audits
- Other Monitoring and Audit activities

Other – Minnesota specific

- Medicaid (Department of Human Services)
  - Triennial of HMOs
    - Minnesota Department of Health / Minnesota Department of Human Services
  - Ongoing monitoring and reviews
- Office of the Minnesota Legislative Auditor (OLA)
  - Review of Minnesota Premium Subsidy
  - Ramp up in Encounter Data Reviews
    - Pharmacy
    - Behavioral Health
    - Dental
Audit Readiness

**Bottom Line: Setting clear expectations is critical; this is not rocket science**

- Executive Endorsement and Strong Culture of Compliance
  - **Tips:**
    - *All-company meetings*
    - *Ad hoc trainings in addition to annual HIPAA, FWA, and HR web-based trainings*
    - *Executive participation in compliance committee and board reporting framework*
- Audit Administration Framework / P&Ps
  - Annual Audit Plan
  - Audit Administration process – including communication protocols, defined POCs
- Audit Preparedness Dashboards
  - *Eyes Wide Open approach – no surprises*
  - Track results of internal audit work and organizational risk assessments
  - Socialize audit risks with business leads to ensure appropriate prioritization

**Audit Readiness**

- Develop process for keeping current on audit guidelines – regulatory agencies are rarely secretive about what is expected
  - Audit tools are regularly published/refreshed (NAIC Market Regulation Handbook; CMS Part C & D Audit Protocols)
  - Review previous years CMS Audit results and enforcement action reports
    - Identify trends in areas auditors are focusing
    - Identify commonly identified issues by other plans
      - Failure to check OIG exclusion list
      - Inadequate FWA training
      - Coverage determination misclassifications
      - Failure to address all issues raised in org. determination grievances
  - Perform periodic mock data pulls / align with known areas of risk
Audit Readiness

- **Hire a third-party to perform comprehensive mock audit**
  - There is no substitute for practicing under simulated audit conditions/timelines
  - Mimic real audit conditions to the extent possible – perform via webinars.
  - Put mock audit work out to bid – evaluate firm’s familiarity with audit trends
  - Executive buy-in and organization prioritization of mock audit work is critical
  - Act immediately on audit results – don’t just file the audit reports away for the future

Go Time – Organizing an Audit

- **Goal**: the day your receive an audit notice should be an [exciting?] opportunity to initiate the plan your company has in place
- Assemble internal team to manage audit, based on scope and type of audit
  - Audit Administrator (e.g., Compliance staff, operations, finance)
  - Project Manager
  - Business owner representatives who own audit inputs/outputs (recommendation: choose single owners even when functional area may involve multiple cross functional inputs)
- Establish ground rules for Audit Team
  - All communications must be centralized through Audit Administrator unless delegated to team member
  - Checklist assignments
  - Periodic report-outs to compliance committee and executive staff
Go Time – Organizing an Audit

- Finalize internal checklist and timeline for audit (ideally should have a framework for this prior to initiating audit and just fill in the blanks)
- Establish an audit repository to organize all audit submission materials, communications, and work papers. Assign one individual to manage the repository (likely the Audit PM).
- Do as much as you can ahead of being requested (depending on type of audit and available guidance)
  - Complete questionnaires
  - Compile relevant P&Ps
  - Perform practice data pulls from expected time period
- Schedule practice interviews/data extract webinars with key staff.
- Provide fiercely honest feedback – setting clear expectations and correcting issues early and often is critical. Time is the rarest commodity in a live audit scenario.

How and When to Work with the Legal Team

- Early and keep legal updated on the audit, scope and purpose
- Should you challenge the scope of the audit?
  - Probably not
  - Better luck with negotiating deadlines and document scope
- Considerations to discuss (obtain advice):
  - Potential compliance and legal issues (differences)
  - Full spectrum of risks
    - Legal the strength of the law; compliance the enforcement priorities
    - Fines, Civil Monetary Penalties, Potential for Business Disruption
  - How established is review and what is published for audit tools
    - CMS Program Audit, CMS Risk Adjustment Data Validation Audit, OLA encounter audits
  - How clear are the guidance/regulations at issue
  - Is the audit targeted to your organization or part of an industry review
Preparations Under Privilege?
- Pros/cons and potential risks

During the Audit
- Not in the audit room or on calls (unless regulator has attorney present)
- Review documents prior to submission
  - Trade secret or other confidential status (requiring a “mark”)
  - Other pitfalls with the requirements / interplay with other laws
- Help with ongoing risk analysis

Draft Findings
- Helping to draft audit responses and objections
- Research prior regulatory positions; statutes and sub-regulatory guidance
- Document your position – often

How and When to Work with the Legal Team (continued)

Challenges to Findings
- How clear is the guidance?
  - Not yet final and methodology not yet published?
  - What are the financial and operational implications to correcting the finding
  - Is the regulator pushing a new theory in the findings (new CMS RADV audits)
  - Respectful discussion
  - Well constructed written positions
  - May take several times at several levels for success
  - How likely is it the organization will appeal (preservation of position and the record)?

What will your ongoing relationship be with this regulator
  - Don’t lose sight of this!
Lessons Learned

- **Lessons learned:**
  - Do not give up – might not win the issue but can lessen the penalty
  - *And* don’t go too far – remember long term relationship and who holds the cards
  - Don’t do the auditor’s work for them
  - No such thing as too much prep
  - Be prepared for surprises – that can be where legal critical
  - Relationships with regulators matter – invest in face time
  - Have a unified approach with your business leaders for prioritizing audit work
Ethical Considerations in Contract Drafting and Negotiation

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Relevant Rules

- Minnesota Rules of Professional Conduct
- Rule 1.2(d), MRPC
- A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning, or application of the law.
Rules (Cont’d)

- Rule 1.13(b), MRPC
  - If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act, or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then the lawyer shall proceed as is reasonably necessary in the best interest of the organization. Unless the lawyer reasonably believes that it is not necessary in the best interest of the organization to do so, the lawyer shall refer the matter to higher authority in the organization, including, if warranted by the circumstances, to the highest authority that can act on behalf of the organization as determined by applicable law.

Rules (Cont’d)

- Rule 4.1, MRPC
  - In the course of representing a client, a lawyer shall not knowingly make a false statement of fact or law.

- Rule 4.2, MRPC
  - In representing a client, a lawyer shall not communicate about the subject of the representation with a person the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized to do so by law or a court order.
Rules (Cont’d)

Rule 4.3, MRPC

In dealing on behalf of a client with a person who is not represented by counsel:

(a) a lawyer shall not state or imply that the lawyer is disinterested;

(b) a lawyer shall clearly disclose that the client’s interests are adverse to the interests of the unrepresented person, if the lawyer knows or reasonably should know that the interests are adverse;

(c) when a lawyer knows or reasonably should know that the unrepresented person misunderstands the lawyer’s role in the matter, the lawyer shall make reasonable efforts to correct the misunderstanding; and

(d) a lawyer shall not give legal advice to the unrepresented person, other than the advice to secure counsel, if the lawyer knows or reasonably should know that the interests of the unrepresented person are or have a reasonable possibility of being in conflict with the interests of the client.

Rule 4.4, MRPC

(a) In representing a client, a lawyer shall not use means that have no substantial purpose other than to embarrass, delay, or burden a third person, or use methods of obtaining evidence that violate the legal rights of such a person.

(b) A lawyer who receives a document or electronically stored information relating to the representation of the lawyer’s client and knows or reasonably should know that the document or electronically stored information was inadvertently sent shall promptly notify the sender.
Rules (Cont’d)

- Rule 8.3(a), MRPC
  A lawyer who knows that another lawyer has committed a violation of the Rules of Professional Conduct that raises a substantial question as to that lawyer’s honesty, trustworthiness, or fitness as a lawyer in other respects, shall inform the appropriate professional authority.

Rules (Cont’d)

- Rule 8.4(c), MRPC
  It is professional misconduct for a lawyer to:
  - engage in conduct involving dishonesty, fraud, deceit, or misrepresentation.
Scenario #1

► You represent the Seller in an acquisition. Buyer demands your client make a “flat” compliance representation, i.e., Seller, its directors, officers, and employees, are in compliance with all healthcare laws. Your client wants the deal done now and is inclined to give this rep. You know your firm advised your client on responding to a routine state department of health survey of its hospital license. The survey identified deficiencies requiring a corrective action plan.

► Can you agree with your client’s wishes to agree to the rep?
► What other options do you have?

Scenario #2

► Company and Vendor have an agreement in principle. Vendor’s lawyer, Slick, offers to prepare the first draft.
► Slick makes most provisions wildly Vendor-favorable just to cost the other side more legal fees, or knowing that Vendor will not insist on them or just because Slick believes in driving a hard bargain.
► Slick makes broad R&Ws but buries language in the SOW that make them meaningless.
► Slick sticks important provisions in unexpected parts of the contract.
► Slick deliberately chooses ambiguous language for some sections to minimize effect of Vendor’s concessions.
► Has Slick done anything ethically wrong?
Scenario #3

- You have been engaged in a month long negotiation over a professional service agreement. The parties are coming close to a deal. Your client has instructed you she does not want lawyers getting in the way of getting this done. Opposing businessperson emails contract draft to you, your client and her lawyer.
  - Can you "reply to all?"
- You are part of a large acquisition of a multi-state DME company. The investment bankers schedule a group call with both Buyer, who you represent, and Seller. The key Buyer and Seller business representatives know each other well. As the call begins, your client and Seller begin negotiations. You do not hear Seller’s counsel on the line.
  - Should you proceed? Can you proceed?

Scenario #4

- Party A discovers that Party B has omitted a material provision to an agreement between the parties. This omission favors Party A, who knows the provision is important to Party B.
  - What is the lawyer’s obligation to point out the mistake?
Scenario #5

▶ You are in-house counsel for Large Healthcare Company A in the Twin Cities. Your newest assignment is to negotiate and close a contract for your employer with Provider B. Prior to your employment, you worked at a law firm and represented Provider B on similar contracts.

▶ Is there a conflict?

Scenario #6

▶ You represent Buyer in the acquisition of a regional home health agency company. You successfully include the following in the purchase agreement:

▶ The rights of Buyer to indemnification shall not be impacted or limited by any knowledge Buyer may have acquired, or could have acquired, nor by any investigation or diligence by Buyer. Seller acknowledges that, regardless of any investigation made (or not made) by or on behalf of Buyer, Buyer has entered into this Agreement in express reliance upon the representations and warranties of Seller made in this Agreement.

▶ In the course of reviewing thousands of pages of diligence, you notice Seller has received multiple notices of alleged contractual breach from vendors, in spite of Seller’s representations to the contrary. Your client says “Excellent! We didn’t want those vendors anyway, and the bonus is we’ll recover some of the purchase price!”

▶ Do you have to report yourself to Susan?
Scenario #7

- You represent a gerontologist in negotiating medical director agreements with five different skilled nursing facilities. Throughout the negotiations and drafting, you structured each agreement to meet the Anti-Kickback Personal Services Safe Harbor. On the verge of signing the agreements, your client sends you an email “Thanks for your work! This will help supplement my income, and these SNFs are great places for my patients!”

- Can your client sign the agreements?

Scenario #8

- You are in-house counsel for a large hospital system. The hospital is challenged by specialists moving more of their surgeries to ambulatory surgical centers.

- Previously, an outside firm helped set up part-time employment agreements with some gastroenterologists. The hospital wants to use the same part-time employment forms with a group of orthopedic surgeons, but with some changes (e.g., 10 year term, full med-mal coverage, benefits, productivity bonus). A consulting firm states the compensation is “fair market value.” One of the doctor’s attorneys sends you a memo identifying concerns about the valuation.
Scenario #8 (continued)

The parties agree to ask a national expert and former OIG attorney her thoughts. She said the agreements raise red flags.

Your new outside counsel emails you the following:

“We’ve had experiences with third party attorneys very much like this case in two other deals, and it just slows it down and makes it horribly complicated. We get lawyers involved who are not committed to the deal. They’re only committed to making the deal safe so we end up stripping out all the business terms that achieve the intended result.”

What do you do?

ABA Opinion 481

A Lawyer’s Duty to Inform a Current or Former Client of the Lawyer’s Material Error

Model Rule of Professional Conduct Rule 1.4 requires a lawyer to inform a current client if the lawyer believes that he or she may have materially erred in the client’s representation. Recognizing that errors occur along a continuum, an error is material if a disinterested lawyer would conclude that it is (a) reasonably likely to harm or prejudice a client, or (b) of such a nature that it would reasonably cause a client to consider terminating the representation even in the absence of harm or prejudice. No similar obligation exists under the Model Rules to a former client where the lawyer discovers after the attorney-client relationship has ended that the lawyer made a material error in the former client’s representation.
Advisory Opinion Service

- Available to licensed MN attorneys
- OLPR attorneys will provide no cost verbal opinion on application of specific facts to rules; every day an attorney is assigned to A/O tasks and spends much of the day returning calls; will receive answer the same day or next day
- Confidential; non-binding on third parties
- No opinion will be offered on (1) conduct of third parties, (2) where conduct has already occurred, and (3) OLPR does not approve lawyer advertising, but will advise rules relating to same
- In 2017, the OLPR provided 2051 opinions.
- Options: Submit a written request on line (preferred where facts are complicated or detailed); call 651-296-3952 or toll-free 1-800-657-3601 and ask for the A/O attorney
- Website: [http://lprb.mncourts.gov](http://lprb.mncourts.gov)

Additional Resources

- Wealth of Resources on Website, [http://lprb.mncourts.gov](http://lprb.mncourts.gov)
- Index and text of Bench and Bar articles and MN Lawyer ethics columns by Office, sorted by Rule, Subject and Year (no precedential value but useful guidance)
- Current Rules (MRPC and RLPR) and Board Opinions
- Suspended and Disbarred Lawyer List
- Attorney Search containing all public discipline, with links to Court opinions and petitions for discipline
- Trust Account Information and Resources, including FAQs
- Professional Firm Filing Requirements
- Cross Border (Multijurisdictional Practice) Information
- Annual Reports of OLPR, including historical reports
- Announcements and News
- Board and Office Directory
- Complaint forms in English, Hmong, Russian, Somali, and Spanish
Beyond the Basics: How to Handle Tough Breach Questions

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Beyond the Basics: How to Handle Tough Breach Questions

This session assumes a working knowledge of breach-response protocol. By way of real-world types of examples, this session will tackle specific, tough questions that privacy/security lawyers encounter including: does the notification clock start ticking when an incident is suspected but not confirmed; what to do if the incident plan isn’t working; and are there situations when proactively providing notice is a good idea (even if it is not required).

– Mitchell W. Granberg & Anna Shimanek

The information contained in these CLE materials should not be construed as legal advice or legal opinion on specific facts, and should not be considered representative of the views of Optum, CVS Health or any of their lawyers.
Did the incident involve PHI?

Yes

Was the PHI encrypted or otherwise secured?

No

Notice not triggered under HIPAA

Yes

Perform state law analysis

No

Conduct four factor risk assessment to determine probability of compromise

Does one of the three exceptions apply to the definition of breach?

- Unintentional disclosure to a workforce member of CE/BA acting in good faith (e.g., provider accesses wrong chart)?
- Inadvertent disclosure to another workforce member of the CE/BA (e.g., emailed to wrong provider at MC)?
- Good faith belief that unauthorized recipient would not have been able to retain (e.g., immediately returns wrong bag to pharmacy)

Yes

First Factor
The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification

Name + Medication?
Name + Contact information?
Name + financial or insurance information?

Second Factor
The unauthorized person who used the PHI or to whom the disclosure was made

Was the recipient another CE?
Does the recipient have an obligation to protect the PHI (for example, a physician’s office, health plan)?
Does the recipient have a relationship with the patient?

Third Factor
Whether the PHI was actually acquired or viewed

Did the recipient receive the PHI?
Did the recipient look at the PHI?

Fourth Factor
The extent to which the risk to the PHI has been mitigated

Satisfactory assurances the PHI would not be further used or disclosed?
Returned or securely destroyed?
Workforce member retrained/disciplined?

Probability of Compromise = Yes
HIPAA notice obligations have been triggered

Probability of Compromise = No
HIPAA notice obligations have not been triggered
State Law Guidance

Did the breach occur in one or more of the following states and involve health information (definition may be broader than HIPAA):

Arkansas
California
Connecticut
Delaware
Missouri
Montana (insurance policy #)
Nevada (health insurance #, Medicaid account #)
Texas
Puerto Rico

State Law Not Triggered

Did breach occur in one or more of the following states:

Alaska
Hawaii
Indiana (non-electronic info if originally in computerized)
Massachusetts
North Carolina
South Carolina
Wisconsin

and include computerized/electronic information

Refer to state law for notice requirements

Additional Notification Requirements
Does the notification clock start ticking when an incident is suspected but not confirmed? Or does the 60 days start upon discovery of a potential breach?

The HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured protected health information. Similar breach notification provisions implemented and enforced by the Federal Trade Commission (FTC), apply to vendors of personal health records and their third party service providers, pursuant to section 13407 of the HITECH Act.

And when does the clock for breach notification start ticking? Again, many covered entities and business associates unwittingly find themselves out of compliance by assuming the obligation to report without unreasonable delay begins on the day they determine a breach occurred. The reporting period actually begins earlier, when the entity learns about an “incident”—an acquisition, access, use, or disclosure of PHI that is impermissible under the HIPAA Privacy Rule—that it subsequently investigates. OCR emphasizes:

Section 13402(d) of the Act and the implementing regulations at § 164.404(b) require covered entities to notify individuals of a breach without unreasonable delay but in no case later than 60 calendar days from the discovery of the breach, except in certain circumstances where law enforcement has requested a delay. Under this rule, the time period for breach notification begins when the incident is first known, not when the investigation of the incident is complete, even if it is initially unclear whether the incident constitutes a breach as defined in the rule. A covered entity is expected to make the individual notifications as soon as reasonably possible after the covered entity takes a reasonable time to investigate the circumstances surrounding the breach in order to collect and develop the information required to be included in the notice to the individual. The 60 days is an outer limit and therefore, in some cases, it may be an “unreasonable delay” to wait until the 60th day to provide notification. HIPAA Omnibus Final Rule, 78 Fed. Reg. 5648 (January 25, 2013).

Are there situations when proactively providing notice is a good idea (even if it is not required)?

Yes! Covered entities and business associates, where applicable, have discretion to provide the required breach notifications following an impermissible use or disclosure without performing a risk assessment to determine the probability that the protected health information has been compromised. https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html

What do I do if the incident plan isn’t working?

Fake it until you make it! (And then revise your plan for the next time.)

Is it possible to conduct the investigation under privilege when cooperating with law enforcement?

Yes! But you need to be careful about how the disclosure is made to ensure you maintain privilege over the investigation, especially if you are engaging local or state law enforcement.

Congress passed the Cybersecurity Information Sharing Act of 2015 (“CISA”), 6 U.S.C. §§ 1501–1510, which enables companies to share information with the federal government concerning “cyber threat indicators” or “defensive measures” without waiving applicable privileges provided they first remove personal identifying information. Section 105(d)(1). There is no analogous provision for sharing with state and local governments or other companies.

To utilize CISA’s non-waiver protections, keep legal and business functions separate in cyber investigations, and are ensure that work performed by third parties and other non-attorneys is done in support of a legal investigation and at the direction of counsel.
For local or state law enforcement, while CISA’s provisions do not protect against waiver, there are steps you can take to reduce the risk of waiver including ensuring you only disclose facts (no analysis of root cause) and try to provide oral briefings versus written, to the extent possible.

These steps cannot, however, create a privilege where it has already been waived or did not exist in the first place.

In re Premera Blue Cross Customer Data Security Breach Litigation, Case No. 3:15-md-2633-SI, 2017 WL 4857596 (D. Or. Oct. 27, 2017), the company used a third-party data security consultant to conduct a review of the company’s data management system, which resulted in the discovery of certain malware. Thereafter, the company retained outside counsel and entered into an amended statement of work with the consultant, stipulating that all future work be supervised by counsel. That revised SOW neglected to change the scope of the work, however. The court was not convinced that the remediation report and related documents prepared by the consultant were created “because of” anticipated litigation or would not have been created in substantially similar form but for the prospect of litigation, and because the burden is on the party asserting the privilege, the court concluded that the report could not be withheld.

In re Experian Data Breach Litigation, Case No. 8:15-cv-01592 (C.D. Cal. May 18, 2017), denied a motion to compel production of documents related to an investigation performed by a third-party data security consultant where, in the wake of the breach, Experian’s outside counsel retained the consultant to conduct an expert report analysis to assist counsel in providing legal advice to Experian. Although Experian had previously worked with the third-party data consultant, that fact was irrelevant to the court’s determination because the work previously performed by the consultant was “separate” from the work performed after the breach, which had been done at the direction of counsel.

Another way to address these risks is to have two entirely separate investigations. For example, when Target had its breach, it conducted two parallel investigations—an internal breach investigation, the results of which were not privileged, and an external breach investigation, overseen by counsel and involving a third-party expert retained through counsel, the results of which were privileged since the latter was developed for the express purpose of facilitating counsel’s legal advice. Upon in camera review, the court recognized the privilege and denied the motion to compel production of documents related to Target’s second investigation. In re Target Corp. Customer Data Security Breach Litigation, MDL No. 14-2522 (PAM/JJK), 2015 WL 6777384 (D. Minn. Oct. 23, 2015).
Medicare Advantage and Part D Update

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A Summary of Key Changes to Medicare Advantage and Part D Plans for 2019, 2020 and 2021

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Medicare Advantage

A. Uniformity of Benefits Flexibility

1. Existing Regulation—42 C.F.R. § 422.100 requires that a Medicare Advantage plan (“MA plan”) offer the plan to all Medicare beneficiaries residing in the service area of the MA plan at a uniform premium, with uniform benefits and level of cost sharing throughout the plan’s service area. Historically, CMS interpreted this provision to mean that all members within a plan must pay the same premium, have the same benefits, and the same cost sharing for those benefits.

2. CMS’s New Interpretation—In the 2019 Medicare Program and Part D Policy and Technical Changes Final Rule, CMS reinterpreted its uniformity rule to allow MA plans to offer reduced cost sharing for certain benefits, tailored supplemental benefits, and lower deductibles to members that meet specific medical criteria (based on health status or disease state), provided similarly situated enrollees are equally treated.¹
   i. Justification—CMS said it’s reinterpretation of the uniformity requirement is consistent with the underlying Part C statutory requirements because targeted supplemental benefits and cost sharing reductions must be offered uniformly to all enrollees with a specified health status or disease state.²
   ii. Marketing—Plans can also market the additional benefits to potential enrollees.³
   iii. Non-Discrimination—Plans are still prohibited from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. CMS will review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations.⁴

3. Additional Flexibility for Special Supplemental Benefits for the Chronically Ill (SSBCI)
   i. Bipartisan Budget Act of 2018 (“BBA”)—The BBA authorized waiver of the uniformity requirement beginning in 2020 for MA plans that provide additional supplemental benefits to chronically ill enrollees.⁵
   ii. Definition of Chronically Ill Enrollees—These are individuals who:

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¹ Medicare Program, Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for Service, the Medicare Prescription Drug Benefit Programs and the Pace Program (April 16, 2018), 83 FR 16640, 16480.
² Id.
³ Id. at 16484.
⁴ Id. at 16481.
1. Have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limit the overall health or function of the enrollee;
2. Have a high risk of hospitalization or other adverse health outcomes; and
3. Require intensive care coordination.6

iii. CMS will consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the definition of chronically ill enrollee.7

iv. The Special Supplemental Benefits for the Chronically Ill (“SSBCI”) do not need to be primarily health related.8

1. MA plans have broad discretion to determine what they offer as SSBCI as long as the benefits have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic illness.9
   a. This can include items and services that include capital or structural improvements (e.g., permanent rams, and widening hallways or doorways).
2. Cannot be items or services covered by original Medicare.10

B. Telehealth

1. Old Rule—Previously, MA plans could include additional telehealth services (telehealth benefits beyond what Original Medicare allows) only as a supplemental benefit to be paid for with rebate dollars or enrollee premiums.

2. BBA—As a result of the BBA, starting with the 2020 plan year, MA plans can include most telehealth services as part of the basic benefit package.11
   i. Definition—Under the BBA “additional telehealth benefits” are:
      1. Services for which benefits are available under Medicare Part B but are not payable under 42 U.S.C. § 1395m(m) due to the conditions for payment under such section; and
      2. Have been identified by the MA plan as clinically appropriate to furnish through electronic information and telecommunications technology

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8 Id. at 188.
9 Id. at 188.
10 Id. at 189.
when a provider providing the service is not at the same location as the plan enrollee.\textsuperscript{12}

ii. Enrollee Choice—If MA plans cover a Part B service as an additional telehealth benefit, the MA plan must also provide access to that service through an in-person visit.\textsuperscript{13}


i. Electronic Exchange—CMS defines this as electronic information and telecommunications technology.\textsuperscript{14}

1. CMS did not propose specific text that defines or provides examples of electronic information and telecommunications technology because they believe what is needed will vary based on the service offered.

2. CMS provided some examples of electronic information and telecommunications technologies, such as secure messaging, store and forward technologies, telephone, videoconferencing and other internet enabled technologies.\textsuperscript{15}

ii. Providers—Additional telehealth benefits can only be furnished through contracted providers.\textsuperscript{16}

iii. Enrollee Communication—MA plans must advise each enrollee that the enrollee may receive the specified Part B service(s) at the election of the enrollee.\textsuperscript{17}

4. Additional Guidance—

i. MA plans can still offer MA supplemental benefits (benefits not covered under original Medicare) via remote access technologies and telemonitoring for services that do not meet the requirements under original Medicare or the requirements for MA additional telehealth benefits.\textsuperscript{18}

ii. In the Final Rule, CMS did not adopt its proposal to require MA plans to use their provider directories to identify the providers offering services for MA additional telehealth benefits and in-person visits or offering services exclusively for MA additional telehealth benefits. CMS said it will address any provider directory elements pertaining to plans offering MA additional telehealth benefits in future sub-regulatory guidance. Because the providers of MA

\textsuperscript{12} 42 U.S.C. § 1395w-22(m)(2)(A)(ii).
\textsuperscript{13} 42 U.S.C. § 1395w-22(m)(4).
\textsuperscript{14} Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly(PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (April 16, 2019), 84 F.R. 15680, 15829.
\textsuperscript{15} Id. at 15684.
\textsuperscript{16} Id. at 15829.
\textsuperscript{17} Id.
\textsuperscript{18} Id. at 15683-15684.
additional telehealth services must be contracted providers, CMS expects that they will be identified as contracted providers in provider directories.

iii. CMS stated that plans must advise each member that they may receive the Part B service via in-person visit or electronic exchange, but removed the proposed requirement to put this in the EOC and said it will issue future sub-regulatory guidance regarding the requirement.

iv. CMS said it will consider the comments it received with regard to using telehealth providers to meet network adequacy requirements as it conducts further research on the issue and updates its sub-regulatory guidance.

C. Restoration of MA Open Enrollment Period: Consistent with the 21st Century Cures Act, CMS eliminated the existing MA disenrollment period and replaced it with a new MA open enrollment period (OEP) that will take place from January 1 to March 31 each year.19

1. The new OEP allows beneficiaries enrolled in an MA plan to make a one-time election to change to another MA plan or Original Medicare during the first 3 months of the calendar year. Newly eligible individuals who enroll in a MA plan can switch MA plans or obtain coverage through Original Medicare during the first 3 months they have both Part A and Part B.

2. Enrollees can change their Part D coverage only to the extent they are enrolled in an MA plan. For example, an individual in an MAPD plan can use the OEP to switch to: (1) another MAPD plan, (2) an MA only plan; (3) Original Medicare with our without a PDP.20

3. Plans are prohibited plans from “knowingly” marketing to eligible beneficiaries during the OEP.21

D. Part C and Part D Preclusion List—Providers are no longer required to be enrolled in Medicare to provide payment from MA and Part D plans for services/drugs provided to members of these plans. However, MA and Part D plans are prohibited from making payment to prescribers, individuals or entities that are on CMS’s “Preclusion List.”22

19 21st Century Cures Act, H.R. 34, 114th Congress; Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Federal Register 16440, 16723.

20 21st Century Cures Act, H.R. 34, 114th Congress; Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Federal Register 16440, 16616.

21 21st Century Cures Act, H.R. 34, 114th Congress; Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Federal Register 16440, 16736.

22 Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost
1. The Preclusion List is a list of prescribers and individuals or entities who fall within any of the following categories:
   i. Are currently revoked from Medicare, are under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
   ii. Have engaged in behavior for which CMS could have revoked the prescriber, individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Such conduct includes, but is not limited to, felony convictions and Office of Inspector General (OIG) exclusions.23

2. Providers are able to appeal and challenge CMS’s placement of the provider but cannot challenge the underlying reason for the revocation, OIG exclusion, or other adverse action that led to their inclusion on the Preclusion List. 24

3. MA plans are required to notify beneficiaries if they have received prescription drugs in the past 12 months from a provider that is being added to the Preclusion List. The notification will allow a 60-day period for beneficiaries to may make arrangements to receive prescriptions from another provider who is not precluded. 25

E. Meaningful Differences in Bid Submissions—CMS eliminated the meaningful difference requirement beginning with bids for 2019. Prior to this rule change, CMS would only approve a bid submitted by a MA or Part D plan if its plan benefit package was substantially different from those of other plans offered by the organization in the same area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered.

   1. CMS’s stated reason for the change was to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation.26

F. Medicare Advantage Value-Based Insurance Design (VBID) Model

   1. MA-VBID is an Innovation Center model, authorized under § 1115A of the Social Security Act (§ 3021 of the Affordable Care Act (ACA). Began in January 2017 and operational through 2024. The model was originally tested in seven states but has expanded (in part

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23 Id. at 16722, 16728.
24 Id. at 16642.
25 Id. at 16660.
26 Id. at 16490-16491.
through Congressional mandate under BBA 2018) to all 50 states. The model is testing how different service delivery innovations in telehealth can be used to both augment and complement an MA plan’s current network of providers, as well as how access to telehealth services may appropriately allow MA plans to expand their service area to currently underserved counties where current MA network adequacy requirements could not be met without the use of telehealth.

2. Model Design – The model waives the “uniformity requirement” and initially allowed Medicare Advantage Organizations to offer varied plan benefit design for enrollees that fall into the following clinical categories: diabetes, congestive heart failure, chronic obstructive pulmonary disease, past stroke, hypertension, coronary artery disease, and mood disorders. Participants design interventions for each targeted population but must fit into four broad categories: (1) reduced cost-sharing for high-value services, (2) reduced cost-sharing for high-value providers, (3) reduced cost-sharing for enrollees participating in disease management or related programs, and (4) clinically targeted additional supplemental benefits. Changes to benefit design made through this model may only reduce cost-sharing and/or offer additional services; targeted enrollees can never receive fewer benefits or have to pay higher cost-sharing than other enrollees because of the model. Includes the following waivers of Medicare payment rules:
   i. Uniformity and Accessibility of Benefits27 - To permit organizations to offer supplemental benefits to the clinically targeted enrollee population, rather than to the entire membership.
   ii. Uniform Cost-Sharing28 - To permit organizations to offer reductions in cost-sharing to the clinically-targeted enrollee population, but not to the entire membership.
   iii. Communications, Disclosures and Marketing29 - For organizations to comply with model-specific guidance on communications, including disclosures, marketing, and communications with enrollees.

3. Model Revisions –
   i. Additional targeted clinical conditions: rheumatoid arthritis, dementia, lower back pain, chronic kidney disease, obesity/pre-diabetes, asthma, tobacco use.
   ii. Additional intervention categories:

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27 SSA §§ 1852(d)(1)(A) [42 USC §§ 1395w-22(d)(1)(A)]; 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2) & 422.254(b)(2); SSA § 1860D–2(a) [42 USC § 1395w-102(a)]; 42 C.F.R. §§ 423.104(b)(2), 423.265(c).
28 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2), 422.254(b)(2) 422.262(c)(1); SSA § 1860D–2(a), 42 USC § 1395w-102(a); 42 C.F.R. §§ 423.104(b)(2) & 423.265(c)
29 SSA § 1852(c)(1)(B) & (F) [42 USC §§ 1395w-22(c)(1)(B) & (F)]; 42 C.F.R. § 422.111(a) & (b); SSA § 1860D–4(a)(1)(A) [42 USC § 1395w-102(a)]; 42 C.F.R. § 423.128(a) & (b)(2).
1. VBX by condition, socioeconomic status, or both (including for “non-primarily health related” items or services)\textsuperscript{30}
2. MA and MA Part D rewards and incentives programs\textsuperscript{31}
3. Telehealth networks (including to meet network adequacy requirements)\textsuperscript{32}
4. Wellness and health care planning
   iii. Now allows participation from all Special Needs Plan (SNP) types.

4. Future Revisions – Beginning in 2021, the model will also test including the Medicare hospice benefit in MA.

Stars

A. Contract Consolidation—CMS implemented the ACCESS Act’s requirement that for contract consolidations approved on or after January 1, 2019, the surviving contract’s Star Rating will be an enrollment weighted average of all the combined contract ratings.\textsuperscript{33}

B. Limiting Changes to Advance Notice/Call Letter—Historically, the Part C and D Star Ratings methodology was adopted and updated through the Part C and D Call Letter, with additional guidance issued in annual Technical Notes. Starting with the 2021 Star Ratings, any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes will be proposed and finalized through rulemaking.\textsuperscript{34}

C. New Measures on Display Page—New measures will be kept on the Display Page for a minimum of two years.\textsuperscript{35}

Part D

A. Comprehensive Addiction and Recovery Act of 2016 (CARA)—CMS implemented the provisions of CARA that limit access of beneficiaries who are at risk for abuse of controlled substances to a

\textsuperscript{30} Limited waiver of §§ 1852(a)(3)(D)(i), (ii)(l) and (iii) of the Act [42 USC §§ 1395w–22(a)(3)(D)(i), (ii)(l) and (iii)] and any implementing regulations.

\textsuperscript{31} Limited waivers of 42 C.F.R. §§ 422.134(b)(1), (b)(2), (c)(1)(i) and (c)(1)(ii), related to availability and eligibility for rewards and incentives; 42 C.F.R. § 422.134(c)(1)(i), related to completion of the entire activity or service prior to receiving the reward and incentive; 42 C.F.R. § 422.134(c)(1)(iii), related to the monetary limit on rewards and incentives

\textsuperscript{32} Limited waiver of § 1852(d) of the Act [42 USC § 1395w-22(d)]; 42 C.F.R. § 422.112.

\textsuperscript{33} Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Federal Register 16440, 16726.

\textsuperscript{34} Id. at 16727.

\textsuperscript{35} Id.
selected prescriber(s) and/or network pharmacy(ies) by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy.36

B. Full Benefit Dual Eligible SEP—Full benefit dual eligible beneficiaries now only have a special election period once per calendar quarter during the first nine months of the year instead of being able to change Part D plans once a month.37

C. Protected Class Drug Formulary Management

1. CMS finalized a codification of its existing policy that permits Prior Authorization (PA) and Step Therapy (ST) requirements for protected class Part D drugs. As finalized, Part D plans can apply PA and ST for new starts only (i.e., enrollees initiating therapy) to determine if a drug’s intended use is for a protected class indication, to ensure clinically appropriate use, and to promote utilization of preferred formulary alternatives, or a combination thereof, for five of the six protected classes (the exception continues to be prohibited for antiretroviral medications).

2. CMS did not finalize its proposal to broaden the permissible use of PA and ST for enrollees on existing therapy. CMS concluded that the potential disruption to stabilized patients who were receiving protected class drugs did not outweigh the potential clinical and cost benefits.

3. CMS did not finalize its proposed exceptions to allow Part D sponsors the ability to exclude a protected class drug from a formulary if the drug is a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market, or to exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look back period.38

D. Prohibition Against Gag Clauses in Pharmacy Contracts

1. Effective Part D Sponsors may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee’s Part D plan.39

36 Id. at 16739-16733.
37 Id. at 16737.
38 Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 84 F.R. 23832, 23834-23847 and 23883.
39 Id. at 23883.
E. E-Prescribing and the Part D Prescription Drug Program

1. No later than 2021, Part D plans must implement one Real Time Benefit Tool (RTBT) that is capable of integrating with at least one prescriber’s e-Prescribing system or electronic health record.\textsuperscript{40} CMS noted that requiring patients to provide explicit affirmative consent before each use of an RTBT is unnecessary.\textsuperscript{41}

F. Part D EOB

1. Beginning in 2021, Part D sponsors must include negotiated price increases and lower cost therapeutic alternatives in Part D EOBs.\textsuperscript{42}
2. The negotiated price information required to be included in the Part D EOB is the percentage increase in the total cost for each prescription, when there is an increase, since the first claim of the current benefit year for each prescription drug claim in the EOB, which would display under each medication.\textsuperscript{43}
3. Plans can take into account relevant beneficiary-specific information, such as diagnosis, the indication for the prescription and completed step therapy or exception requests, when providing formulary alternatives in the Explanation of Benefits (EOB) that have lower cost-sharing.\textsuperscript{44}

G. Medicare Advantage and Step Therapy for Part B Drugs

1. CMS finalized its Part B Step Therapy rule as proposed, with a few minor changes, such as a lookback period of 365 days instead of 108 days. Some of the highlights include:
   i. Savings realized from Part B step therapy must be reflected in the plan’s bid for 2020 and in the future.
   ii. Part C rebate dollars associated with the lower bid, as with all Part C rebate dollars, must be used to provide supplemental benefits and/or lower premiums for the plans’ enrollees.
   iii. MA plans will be required to administer the existing organization determination and appeals processes under new time frames that are similar to the timeframes applicable in Part D for coverage determinations. Enrollees will be able to seek organization determinations in advance.
   iv. MA plans that apply step therapy to Part B drugs must disclose that Part B drugs may be subject to step therapy requirements in the plan’s Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) documents.

\textsuperscript{40} Id. at 23883-23884.
\textsuperscript{41} Id. at 23851.
\textsuperscript{42} Id. at 23883.
\textsuperscript{43} Id. at 23852.
\textsuperscript{44} Id. at 23853.
v. CMS will allow plans to utilize existing Part D P&T committees.

vi. Plans can only apply step therapy to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication, determined by a look-back period of 365 days. Step therapy cannot disrupt enrollees’ ongoing Part B drug therapies.

vii. Plans can require an enrollee to try and fail an off-label medically-accepted indication before providing access to a drug for an FDA-approved indication (on-label indication) when such drugs are supported by widely used treatment guidelines or clinical literature. CMS noted that NCCN would be a good source of treatment guidelines for this purpose.45

H. Pharmacy Price Concessions in the Negotiated Price

1. CMS did not finalize its proposal to require plans to pass through pharmacy price concessions to members at the point-of-sale, although it received over 4,000 comments on it. CMS stated it will “carefully review all input received from stakeholders on this issue as we continue our efforts to meaningfully address rising prescription drug costs for beneficiaries.46

I. Enhanced Medication Therapy Management (MTM) Model47

1. eMTM is an Innovation Center model. The model is a five-year model for stand-alone PDPs that began January 1, 2017 and that operates in 5 Part D regions.

2. Model Design - Participants are given regulatory flexibility to create plans that vary the intensity and types of MTM items and services based on beneficiary risk level and that provide individualized beneficiary and prescriber outreach and engagement. The goal of the model is to identify and engage beneficiaries whose issues with medication management have caused, or are likely to cause, adverse outcomes and/or significant non-drug program utilization and costs.

J. Part D Payment Modernization Model48

1. In January 2020 the Innovation Center will launch the Part D Payment Modernization model, which will test the impact of a revised Part D program design and incentive alignment on overall Part D prescription drug spending and beneficiary out-of-pocket costs.

45 Id. at 23879-23883.
46 Id. at p. 23834.
47 See https://www.cms.gov/newsroom/fact-sheets/participants-selected-part-d-enhanced-medication-therapy-management-model.
48 See https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/.
2. Model Design - The five-year voluntary model will be available to both PDPs and MA-PDs and offers new incentives for plans, patients, and providers to choose drugs with lower list prices to address catastrophic phase costs. CMS will create a spending target benchmark for each participant that represents the catastrophic phase costs CMS projects it would have paid if the participant was not in the model. If annual catastrophic phase spending is lower than the benchmark, the plan will share in the savings generated. If spending is higher than the benchmark, the participant will repay 10% of the amount above the benchmark.

Integration Requirements for Dual Eligible Special Needs Plans

A. Model Integration

1. The BBA requires all DSNPs meet certain new minimum criteria for Medicare and Medicaid Integration for 2021 and subsequent years.

2. Three types of DSNPs can meet the BBA’s integration requirements: 1) FIDE SNPs; 2) HIDE SNPs; and 3) DSNPs that contract with the state Medicaid agency to notify the Medicaid agency or a designee of hospital and SNF admissions for at least one group of high risk members.49

3. CMS also finalized its proposed interpretation of existing statutory language to require DSNPs to take a more active role in coordinating the delivery of Medicaid benefits and indicated that it plans to release subregulatory guidance further clarifying the role of a DSNP in coordinating Medicare and Medicaid services for its members.

   i. CMS did say that it would be insufficient for a DSNP to limit its coordination activities simply to telling a beneficiary to call or write their Medicaid managed care plan or state agency without giving specific contact information, giving specific coaching on the roles of the Medicaid program, and offering addition support as needed.50

4. CMS considered but is not requiring that partial dual eligibles be excluded from DSNPs.51

49 Medicare Program and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE); Medicaid Fee-For-Service and Medicaid Managed Care Programs for Years 2020 and 2021, 84 F.R. 15680, 15702-15703, 15827-15828.

50 Id. at 15702.

51 Id. at 15718.
B. Unified Grievance and Appeals Procedures for DSNPs and Medicaid Managed Care Plans

1. Effective January 1, 2020, all DSNPs will be required to assist all DSNP members with their Medicaid appeals.\(^{52}\)
   i. This is limited to “reasonable assistance in completing forms and procedural steps” specifically to Medicaid appeals and grievances.\(^ {53}\)

2. CMS also finalized a unified appeals and grievance process for applicable integrated plans.\(^ {54}\)
   ii. Any treating provider can request an integrated organization determination and integrated reconsideration.\(^ {55}\)

What’s Still Out There

A. RADV—CMS has proposed to extrapolate data generated from Risk Adjustment Data Validation (RADV) audits dating back to 2011 without the use of a fee-for-service (FFS) adjuster to offset the error rate.

B. Interoperability and Patient Access—CMS has proposed new policies that will expand access to health information and improve the seamless exchange of data in healthcare. CMS hopes to enable better care coordination, better patient outcomes and reduced costs.

C. AKS Rebate Safe Harbors—The Office of Inspector General of the Department of Health and Human Services has a proposed rule pending to eliminate safe harbor protection under the anti-kickback statute for drug price reductions that pharmaceutical manufacturers pay to Medicare and Medicaid plan sponsors and their pharmacy benefit managers.

\(^{52}\) Id. at 15834.
\(^{53}\) Id. at 15725.
\(^{54}\) Id. at 15835-15843.
\(^{55}\) Id. at 15836.
Business Process Outsourcing
Concepts for the Health Lawyer

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4. Key Considerations for Managing the Supplier Post-Signing ...................................................................4
The following outlines important considerations and information to help your organization prepare for a business process outsourcing (“BPO”) arrangement as you structure, negotiate and manage the deal.

1. **Key Legal Terms**

A BPO Master Services Agreement (“MSA”) is similar to other complex services agreements and contains many of the same provisions and considerations. Each outsourcing transaction exists on its own merits and requires careful analysis. However, the following concepts should be considered in detail as a result of the specific challenges faced by health care entities in managing the performance of outsourced services:

   A. **Services Description**

   The description of the outsourced services to be performed by the vendor will typically be detailed in the schedules or statements of work. But the MSA should also contain a broad “Services” definition to limit any contractual gaps between the customer’s expectations and the vendor’s commitments. A broad Services definition therefore functions as a back-stop catch-all statement to avoid unexpected additional fees, where the scope of services may be ambiguous (e.g., where the description of outsourced services in the schedules or statements of work do not contain a level of detail sufficient to document all steps involved in the performance of the services). There are multiple ways to draft a catch-all Services definition. Conceptually, a very broad starting point would be language requiring the vendor to perform all services previously performed in-house by the customer and eliminated as a result of the agreement, and any services not expressly described in the schedules or statements of work, but necessary for the proper performance and delivery of the outsourced services.

   B. **Termination Rights**

   A BPO arrangement often contemplates a long-term relationship. A long-term relationship allows the vendor to leverage the customer-specific knowledge base created through its performance of the outsourced services, to recover its upfront costs. Long-term relationships are also favorable to the customer due to the costs the customer would incur by disengaging and transitioning to a new vendor. Nevertheless, the customer should seek to retain flexibility to bring the outsourced services back in-house if the underlying financial assumptions change (i.e., a right to terminate for convenience) or terminate the services in-whole or in-part if the vendor fails to adequately perform the services. Customer rights to terminate for convenience are generally preferred, but often require payment of early termination fees necessary to off-set the vendor’s upfront costs that the vendor would not recover as a result of the termination. In addition to the standard right to terminate the MSA for material breach, the customer should seek to specify certain key provisions, the breach of which would be deemed a material breach of the MSA, but which would not otherwise meet the legal threshold for a material breach under applicable state law. For a healthcare BPO arrangement, such provisions may include breaches of confidentiality, data security, laws and regulations, and key commercial or regulatory service levels. If the customer terminates an agreement in-part only, the agreement should provide a mechanism for appropriately lowering the fees based on the terminated services.
C. Transition Period

The customer should evaluate the duration and type(s) of outsourced services that the customer would need the vendor to continue to perform following expiration or termination of the agreement to allow the customer to disengage and transition the outsourced services either in-house or to a new vendor. A good measuring stick will be the duration of the procurement process to engage the current vendor. However, several factors, such as technology integration, type of health plan products involved, location of data centers, and ability to transfer the underlying knowledge base necessary to perform the outsourced services may significantly impact the length of time required to transition the services. Accordingly, it is often advisable to include a longer time period than the customer may anticipate to be necessary and allow the customer to shorten the duration if needed. Further, the customer should seek to define the payment terms for services during the transition period to remain at the cost-level applicable prior to termination or expiration of the agreement and to decrease as the customer disengages and transfers the services away from the vendor.

D. Audit Rights

Federal and state law will provide a baseline for the audit rights necessary with respect to regulatory authorities with jurisdiction over the customer’s business. The customer should seek to have the ability to direct vendor compliance in connection with regulatory audits and ensure that all audit rights of regulatory authorities extend to all vendor subcontractors, including their facilities. Regulatory audit rights should not be subject to any limitations on the number of audits that may occur in any given time period (e.g., each year). In addition, the customer should seek to have the unlimited right to audit the vendor and its subcontractors for compliance with the vendor’s obligations under the agreement. For health plan customers, if employer group plans are within the scope of the outsourced services, the customer will also need to retain the right for the employer group plans to, directly or through a third party, audit the vendor and its subcontractors in accordance with the audit rights granted by the health plan to the employer group. If the vendor seeks to limit the number of audits per year, the customer should retain the right to re-audit the vendor and its subcontractors following specified events, including, for example, any deficiency discovery through a prior audit by the customer, through a vendor self-audit or by a regulatory authority.

2. Key Commercial Terms

There are three critical commercial components to any BPO agreement: (i) the services descriptions, (ii) service levels, and (iii) the charges/pricing. Each requires detailed treatment in the contract. Additionally, the proposed service provider’s solution, which should be uniquely tailored to the customer’s specific set of in-scope services, is an important commercial component of the agreement.

Drafting contract appropriate service descriptions can often be a challenge. The service descriptions included in a BPO agreement should be concise and clearly describe the relevant functions that are “in scope.” If there are portions of the scope that will be retained by the customer, the scope should affirmatively state that those functions will not be part of the service provider’s responsibilities. Additionally, avoid designating any joint responsibilities for the services. To the extent that both parties are involved in a function, then one party should be listed
as the “primary” responsibility with the other party in a “support” role. Lastly, to avoid future disagreements, do not draft the services descriptions by referencing/relying on post-effective date artifacts. Documenting scope after contract signature is likely to lead to unanticipated costs and charges.

Service levels, including the applicable methodology for measuring the service levels, computing credits and revising service levels during the term, are an important mechanism for the customer to maintain sufficient control over the quality of service delivery. The universe of service levels applicable to the in-scope services should be tailored to those that (i) provide the customer with an end-to-end assessment of the services, (ii) are required by regulation, (iii) reflect “pain points” or other areas for improvement, and (iv) are critical to the customer’s operations. Effective service levels are tightly tailored to measure just those services within the service provider’s span of control. Customers that can show an existing portfolio of internal service levels to measure the services to be outsourced (including data supporting levels of performance) will be best prepared to transition to an outsourced arrangement.

Details about “how” the Supplier will perform the services should be included in solution documentation incorporated into the agreement. The solution details should specify the tools, processes, and methodologies that the service provider will implement to perform and deliver the services. Service provider marketing material should not be used as a substitute for service provider’s solution to perform the in-scope services.

Sufficiently detailed commercial terms can avoid future ambiguity and the risk of unintended charges under the Agreement.

3. Key Regulatory Considerations in the Healthcare Industry

   A. Regulatory Changes

A vendor’s performance of the outsourced services will need to adapt to on-going changes in the applicable regulatory environment(s). As a result, changes to the outsourced services that are required by a change in law or regulations should be required to be implemented by the vendor no later than the effective date of the applicable law or regulation. To avoid that these critical changes get caught up in a cumbersome change order process, they should be exempt from the standard change order process. In addition, changes required by a change in law or regulations should not result in increased fees to the customer where the vendor is contractually obligated to perform the outsourced services in compliance with applicable laws and regulations (i.e., the cost of compliance should be priced as part of the vendor’s performance of the services). For major changes in applicable law or regulations, it may be reasonable to specify a cost impact to the vendor resulting in re-negotiation of fees (e.g., if the vendor is able to document increased costs in excess of $10 million per year as a result of such change in law or regulations).

   B. Interpretation of Applicable Law

The customer should retain the right to conduct its own regulatory compliance function with respect to the outsourced services. The customer is the responsible party to the relevant regulatory authorities and should not relinquish control of its ability to meet its regulators needs. In addition, a vendor may not have previous experience with Minnesota law, or with respect to Minnesota law
governing the healthcare products subject to the outsourced services. A contractual provision allowing the customer to direct the vendor’s interpretation of applicable laws and regulations may contain certain off-sets to the vendor for any vendor violation of applicable law resulting from a customer directive (e.g., that any such vendor violation of applicable law will not be deemed a breach of the agreement and/or customer indemnification of vendor).

Legal Discovery and Regulatory Inquiries

For certain healthcare BPO arrangement, the vendor may become the sole source of certain information or otherwise be in possession of documents and records relevant to regulatory proceedings or litigation related to the outsourced services. The customer should therefore include contractual obligations for the vendor to make personnel available and comply with requests for information, discovery requests and litigation holds as necessary for the customer to meet its legal and regulatory obligations. Further, the vendor should be obligated to comply within any time-frames required for the applicable regulatory or legal proceeding.

4. Key Considerations for Managing the Supplier Post-Signing

Negotiating BPO arrangements is time consuming and requires significant allocation of customer resources to review and provide input on each draft of the agreement. However, after investing the time and resources to negotiate and execute a detailed contract that reflects each party’s responsibilities and the allocation of risk between the parties, it is critical that the appropriate governance bodies be implemented and contract management practices applied to the relationship. A carefully crafted BPO agreement will include a governance schedule or specific governance terms describing the post-effective date organization for both parties in support of the on-going relationship. Key governance terms within should describe:

- Required ongoing relationship level meetings including the frequency and required attendees from both parties
- Required ongoing management level reporting (including the frequency of delivery) related to the status of the services, charges and service levels
- Day-to-day management structures for the services including the roles within both organization that have responsibility
- Executive level structures for managing the overall relationship
- Dispute resolution mechanisms and escalation processes for addressing issues between the parties during the term
- Benchmarking processes for comparing the services to industry practice during the term
- Processes for integrating new technologies and innovations into the Services during the term
- Change control procedures for modifying the services (and amending the Agreement) during the term

Outside of the governance processes, the customer and vendor should also review certain terms of the agreement on an annual basis (or other regular frequency) to make sure that industry practices and regulatory obligations are continually reflected in the performance of the Services. Some of
the most important provisions to keep current and, as appropriate, amend include terms related to protection of Personal Information, applicable law and audit provisions/standards.
Beyond HIPAA: Health Industry Privacy and Security Update

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Beyond HIPAA: Health Industry Privacy and Security Update

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Topics

(1) California Consumer Privacy Act of 2018
(2) GDPR Applicability
(3) 42 C.F.R. Part 2 Applicability
(3) Minnesota Health Records Act
(4) Quick notes on State AG enforcement
California Consumer Privacy Act of 2018

- Enacted June 28, 2018 with significant revisions September 23, 2018
- California Civil Code §§ 1798-100-1798.199
- Becomes operative January 1, 2020
  - However, CA AG given until July 1, 2020 to adopt regulations to implement the CCPA
  - No enforcement actions by the AG until the earlier of 6 months after final regulations are adopted or July 1, 2020

California Consumer Privacy Act of 2018

- Establishes rights of consumers with regard to their data
- Creates a process for consumers to determine whether (and how) a covered business is holding, selling, and transferring their personal information
- Requires covered businesses to implement processes to maintain consumer data and respond to consumer inquiries
- Exemptions
- Enforcement
California Consumer Privacy Act of 2018

• Who is regulated?
• Key terms are
  – Business
  – Consumer
  – Personal Information
  
  CA Civil Code § 1798.140(c), (g), and (o)
• Health Care Exemptions at CA Civil Code § 179.145(c)

California Consumer Privacy Act of 2018

• Business means
  – A legal entity that
    • is organized or operated for the profit or financial benefit of its shareholders or other owners;
    • collects consumers’ personal information (or on the behalf of which such information is collected) and (alone or with others) determines the purposes and means of the processing of consumers’ personal information;
    • does business in CA; and
    • Meets one or more of the following:
      – annual gross revenues in excess of $25M; or
      – annually buys, receives for commercial purposes, sells, or shares for commercial purposes, the personal information of 50,000 or more consumers, households, or devices; or
      – Derives 50% or more of its annual revenues from selling consumers’ personal information
  – Any entity that controls or is controlled by a Business as defined above, and that shares a name, service mark, or trademark with the Business
California Consumer Privacy Act of 2018

- **Consumer** means a natural person who is a CA resident
- **Personal Information** means information that identifies, relates to, describes, is capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household, such as:
  - real name, alias, address, unique personal identifier, online identifier, IP address, email, account name, SSN, driver’s license number, passport number, or other similar identifiers;
  - Any categories of personal information described in subdivision (e) of Section 1798.80
  - Characteristics of protected classifications under CA or federal law
  - Commercial information, such as personal property records, or consuming histories or tendencies
  - Biometric information
  - Internet or other electronic network activity information, including, but not limited to, browsing history, search history, and information regarding a consumer’s interaction with an Internet Web site, application, or advertisement
  - Geolocation data
  - Audio, electronic, visual, thermal, olfactory, or similar information
  - Professional or employment-related information
  - Education information, defined as information that is not publicly available personally identifiable information as defined in the Family Educational Rights and Privacy Act
  - Inferences drawn from any of the information above to create a consumer profile reflecting the consumer’s preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes

California Consumer Privacy Act of 2018

- **Health Care Exemptions:** CCPA does not apply to
  - Medical Information governed by the CA Confidentiality of Medical Information Act (“CMIA”) or PHI collected by a Covered Entity or Business Associate governed by the HIPAA privacy, security, and breach notification rules
  - A provider of health care governed by the Confidentiality of Medical Information Act or a Covered Entity governed by HIPAA, to the extent the provider or Covered Entity maintains patient information in the same manner as medical information or PHI above
  - Information collected as part of a clinical trial subject to the Common Rule pursuant to either FDA’s human subject protection rules or good clinical practice guidelines issued by the International Council for Harmonisation

CA Civil Code § 1798.145(c)
California Consumer Privacy Act of 2018

• First question: Are you a “Business?”
  – Has to be “organized or operated for the profit or financial benefit of its shareholders or other owners”

• Indicates that a nonprofit corporation is not a Business
  – Nonprofit hospital system that collects personal information about CA patients
    • Should not need to analyze scope of health care exemption
  – Nonprofit medical specialty board, academy, or other credentialing or testing organization that collects personal information about diplomates or others

California Consumer Privacy Act of 2018

• Are you a “Business?”
  – For-profit subsidiary of a nonprofit corporation?
  – For-profit joint venture (with non-profit owners)?
    • Regulations might address this
    • Should be able to analyze the other thresholds (e.g., $25M in gross revenue, etc.) at the JV level
    • If the for-profit JV is a Business under CCPA, you would likely apply the consumer rights and required processes at the JV level
  – What if a non-profit controls a Business and shares a trademark with that Business: the non-profit itself could become a Business
    • In that case, you would also analyze whether (and to what extent) a health care exemption will apply
California Consumer Privacy Act of 2018

• 3 Health Care Exemptions
  – 2 are based on the type of information
    • Certain clinical trial information
    • Medical information governed by CMIA, or PHI collected by HIPAA-regulated entities (CE or BA)
  – 1 is based on the type of entity
    • Provider of health care under CMIA
    • CE under HIPAA

California Consumer Privacy Act of 2018

• Health Care Business Scenarios (assume each relevant entity is a “Business”)
  – Health care service vendor that engages directly with (and collects identifiable health information directly from) consumers
  – Health care service vendor that acts as a Business Associate to its Covered Entity clients, but has clients in other industries
    • The Business Associate could be a Business under the CCPA, and the personal information the BA collects that is not governed by HIPAA would be subject to CCPA
  – Covered Entity is a Hybrid Entity under HIPAA. The Covered Entity is exempt only to the extent it maintains PHI in accordance with HIPAA. Regulated by CCPA to the extent it does not
California Consumer Privacy Act of 2018

• An entity obtains PHI from a CE pursuant to a HIPAA authorization, but is not itself a CE or BA

• A CE collects data from consumers via a website, and does not treat that information in accordance with HIPAA

• As part of its operations, a CE collects (in addition to PHI), demographic and personal information regarding health care clinicians
  – A BA collects or processes the information about clinicians on behalf of one or more CEs

• An entity (e.g., trial sponsor, CRO) collects clinical trial data, but not all trials are conducted in accordance with the Common Rule
  – What if trials are conducted in accordance with the Common Rule by voluntary choice, not because they must be?

California Consumer Privacy Act of 2018

• CCPA’s Privacy Rights for CA Residents
  – Right to know what personal information is collected
    • A consumer may require a Business to disclose to the consumer the categories and specific pieces of personal information that the Business collects, maintains, sells, or transfers CA Civil Code § 1798.110
  – Right to know whether personal information is sold or disclosed, and to whom
    • A consumer can obtain from a Business:
      – The categories of personal information the business has collected
      – The sources from which the personal information is collected
      – The business or commercial purposes for collecting or selling the personal information
      – The categories of third parties with whom the Business shares personal information
      – Specific items or personal information the Business has collected about the consumer
  – Right to say “no” to the sale of personal information
  – Right to access personal information
  – Right to equal service and price
California Consumer Privacy Act of 2018

• Right to say "no" to the sale of personal information
  – Consumer may direct a Business to stop selling the consumer's personal information (i.e., a right to opt-out)
  – Consumer has the right to request that a Business delete any personal information about the consumer (i.e., right to be forgotten)
  – Some exceptions to the right to be forgotten

• Right to access personal information

• Right to equal service and price

California Consumer Privacy Act of 2018

• Obligations corresponding to consumer rights
  – At or before the point of collection, a Business shall inform consumers as to the categories of personal information to be collected and the purposes for which the categories shall be used
  – Online privacy notice shall disclose the consumer’s rights with regard to the consumer’s personal information
    • Including the right to opt-out and the right to be forgotten
    • One or more designated means for consumers to submit requests, including at a minimum a toll-free number and web site address
Other State Privacy Laws

- Nevada: Nevada SB 220. Amendments to existing online privacy law allows consumers to opt-out of sales of consumer information. Exemption for “an entity that is subject to the provisions of [HIPAA]. . .”

General Data Protection Regulation

- Guidance on extraterritorial application of GDPR can be found at: https://edpb.europa.eu/sites/edpb/files/consultation/edpb_guidelines_3_2018_territorial_scope_en.pdf
- Scope of GDPR based on: (1) the “establishment” criterion; and (2) the “targeting” criterion.
Part 2 Rules: Background and Purpose

• The first Confidentiality of Alcohol and Drug Abuse Records regulations were issued in 1975.
• The rules were updated in 1987. Not updated again until 2017.
• Administered by the Substance Abuse and Mental Health Services Administration (SAMHSA), which is part of the Department of Health and Human Services.

Part 2 Rules: Background and Purpose

• **Essential purpose of the part 2 rules:** To ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not more vulnerable because of the availability of their patient record than an individual with a substance use disorder who does not seek treatment.

• **Contrast to HIPAA:** HIPAA is broader, applying to all protected health information held by payers and providers, and seeks to balance privacy and security with availability of records for appropriate purposes.
Part 2 Rules: Basic Principle

• The patient records subject to the part 2 rules may be disclosed or used only as permitted by the part 2 rules
  – May not be otherwise disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority.

• The part 2 restrictions on disclosure and use are unconditional: they apply whether or not the person or entity seeking the information already has it, has other means of obtaining it, is a law enforcement official, or asserts any other justification.

See 42 C.F.R. §2.13(a), (b).

When do the part 2 rules apply?

• The part 2 rules restrict the disclosure and use of substance use disorder patient records maintained in connection with any part 2 program.
  – Not all records that a part 2 program maintains
  – Not all SUD records
  – Not only SUD records held by a part 2 program itself; records maintained in connection with a part 2 program are restricted (even when held by another person or entity).
What is a part 2 program?

- A part 2 program is a federally-assisted SUD program

- What is an SUD Program? Any of the following:
  - An individual or entity that is not a general medical facility who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
  - An identified unit within a general medical facility that holds itself out as providing, and provides substance use disorder diagnosis, treatment, or referral for treatment; or
  - Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

What is a part 2 program?

- An individual or entity that is not a general medical facility who holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment
  - A general medical facility is a medical facility providing a broader set of health services. Hospitals, trauma centers, or federally qualified health centers would generally be considered “general medical facilities.” Primary care physician practices are also “general medical facilities.”
  - “Holds itself out” means any activity that would lead a person to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment, such as
    - Authorization by state or federal government to provide such services, or
    - Advertisements, notices, statements (e.g., web site) regarding SUD services.

- This part of the “program” definition would cover Hazelden clinics and other “freestanding” clinics or programs focused on SUD.
What is a part 2 program?

- An identified unit within a general medical facility that holds itself out as providing, and provides substance use disorder diagnosis, treatment, or referral for treatment.
- This would cover a unit or program within an FQHC that is licensed or certified to provide SUD diagnosis, treatment, or referral for treatment.
  - Other part of the FQHC that do not hold themselves out as providing SUD diagnosis, treatment, or referral for treatment would not be a program.

What is a part 2 program?

- Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.
  - Here, “holds itself out” is irrelevant. If you are clinicians and staff in a general medical facility and you function primarily to provide SUD diagnosis, treatment, or referral for treatment, then you are a program.
  - Other personnel within the general medical facility are not a program.
  - Addiction specialist working within a physician clinic or FQHC.
What is federally-assisted?

- You are federally-assisted if you are provided any license, certification, registration, or any other authorization granted by the U.S. government.
  - Participate in Medicare;
  - DEA registration;
  - SAMHSA-certified Opioid Treatment Program
  - Authorization to conduct maintenance treatment or withdrawal treatment;
  - Receive federal assistance in any form;
  - Tax-exempt.
- Highly likely you are federal-assisted.

What is a part 2 program?

- ABC Treatment Center is a SAMHSA-certified Opioid Treatment Program that provides medication-assisted treatment for patients diagnosed with an opioid use disorder. Dr. Van Heck works at ABC and is registered with the DEA.
- Acme Community Mental Health Center provides both SUD treatment and mental health services. Dr. Tyler is an addiction specialist working at Acme, and only treats patients with SUDs. Dr. Abbott is a psychiatrist working at Acme and treats patients with mental disorders.
- MN Physician Group is a primary care clinic that provides integrated primary care. The group does not in any way advertise that it provides SUD services. It does have a waiver from SAMHSA to prescribe buprenorphine when needed. Dr. Bryant works at the group and occasionally encounters patients with opioid dependence and will provide MAT with buprenorphine when appropriate. She only does this for a handful of patients.
Minnesota Health Records Act

- Karsjens v. Lourey, May 28, 2019, 62-CV-16-5788
  - Damages are an essential element of a claim under both the Minnesota Government Data Practices Act and the Minnesota Health Records Act (Minn. Stat. §§ 144.291 to 144.298)
  - Plaintiff relied on Shgeirat v. U.S. Airways Group, Inc., 515 F. Supp. 2d 984, 998 (D. Minn. 2007), which held that fear of identity theft from disclosure of SSN was sufficient support for an emotional distress claim. But here, Plaintiff put forth no scenario in which any of the medical information at issue could be used to steal his identity.

Benefit of the Bargain Theory

- Missouri has enacted a Merchandising Practices Act, a broad unfair trade practices act. See Missouri Rev. Stat. § 407.010 et. seq.
- Plaintiff alleges that a privacy breach of medical records about the plaintiff resulted in ascertainable loss to Plaintiff based on the "difference between the actual value of the property and what its value would have been if it had been as represented,"
- Court agreed that efforts to maintain privacy and confidentiality of medical records are part of the healthcare services, and that Plaintiff suffered by paying more for medical record privacy protections than she otherwise would have and by paying for medical record privacy protections that she did not receive.
- Privacy and security are part of the benefit of the bargain.
State Attorney General Enforcement

• On December 4, 2018 the attorneys general of 12 states (AZ, AR, FL, IN, IA, KS, KE, LA, MN, NE, NC, and WI) filed a complaint against Defendant Medical Informatics Engineering, Inc., ("MIE"), which operated the WebChart EHR.

• Between May 7, 2015 and May 26, 2015, hackers infiltrated and accessed the computer systems of Defendants. The hackers stole the ePHI of 3.9 million individuals whose health information was contained in an electronic medical records database stored on Defendants' computer systems.

• Requesting unspecified damages to each state and essentially a 5 year privacy and security practices monitoring agreement.

Questions?
Device & Pharma Update: Navigating the Healthcare Landscape in Washington from Congress to the FDA

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Device and Pharma Update: Key Issues and Initiatives

June 19, 2019

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Topic Overview

I. General Overview
   • Political Environment
   • National Health Care Trends

II. Industry Update
   • Drug Pricing
   • Innovation
   • Opioid Epidemic
   • Courts, FDA, Privacy
Political Environment

Reflections on 2018
• The Year of uncertainty

The Rest of 2019
• Amidst ongoing uncertainty
  - Unique White House environment
  - Challenge to move legislation
  - Impact of the changes in the House

• Some points of relative certainty
  - Secretary Azar agenda
  - Impact of upcoming elections
  - FDA agenda
Congressional Agenda - House

House agenda – current focus

Short term (this summer)
- Cosmetic legislation
- Passage of “extenders”
- Health care cost
- Drug pricing
- Opioids

Later in the year
- Diagnostic legislation
- OTC monographs (when returned from the Senate)

Congressional Agenda - Senate

Senate agenda – current focus

Short term (this summer)
- Cosmetic legislation
- Passage of “extenders”
- Health care cost
- Drug pricing
- Opioids

Later in the year
- Diagnostic legislation
- OTC monograph
HHS Certainty - Policy

Key Initiatives

- Value-based medicine and payment
- Drug pricing
- Health care cost
- Opioids

Congressional Uncertainty

- Election uncertainty – what will happen in 2020?
- Other political challenges and issues
  - Consumption of time on other matters
  - Political fallout
  - Budget and debt ceiling issues
General Overview
NATIONAL HEALTH CARE TRENDS

Current State – Rising Cost of Care

Human Compassion
- Social Security
- Medicare
- Medicaid
- Supplemental Security
- CHIP
- Medicare Part D
- PPACA

Economic Dispassion
- National Debt = $20.7 trillion
- Federal Deficit
- Unfunded Liabilities

Source: National Health Care Expenditure Data, The Office of the Actuary in the Centers for Medicare & Medicaid Services
Drug Pricing/Vertical Integration

- CIGNA agreed to buy Express Scripts for a total of $67 billion ($52 billion in cash and stock, $15 billion in assumed debt)
- “When we think about Express Scripts, it has PBM capabilities, but it has 27,000 individuals and a significant number of consumer touchpoints around health and well being,” Cigna CEO David Cordani said in an interview. “It expands our service portfolio beyond that of a PBM.”
- Cigna shareholders will own about 64% of the combined company, which will retain Cigna’s name, and Express Scripts shareholders will own about 36%

Source: WSJ, March 8th, 2018

Market Trends – Horizontal and Vertical Integration

As health care players seek to fend off looming competition and gain economies of scale, the industry has seen a mass of transactions, resulting in increased vertical integration within health care.

Recent Examples of Vertical Integration

<table>
<thead>
<tr>
<th>Players</th>
<th>Industries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigna &amp; Express Scripts</td>
<td>Payer &amp; PBM</td>
</tr>
<tr>
<td>CVS &amp; Aetna</td>
<td>Pharmacy/PBM &amp; Payer</td>
</tr>
<tr>
<td>Albertsons &amp; Rite Aid</td>
<td>Grocer &amp; Pharmacy</td>
</tr>
<tr>
<td>Humana &amp; Kindred</td>
<td>Payer &amp; Provider</td>
</tr>
<tr>
<td>Optum &amp; DaVita Medical Group</td>
<td>Payer &amp; Provider</td>
</tr>
</tbody>
</table>

Key Takeaway
Insurers will be among the most active in vertical integration as they will be better able to carve out “high-cost” hospitals or certain services from contracts.

Select Optum Provider Acquisitions - Since 2011

<table>
<thead>
<tr>
<th>Organization</th>
<th>Provider Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wellmed</td>
<td>Physician group</td>
</tr>
<tr>
<td>MedExpress</td>
<td>Walk-in urgent care</td>
</tr>
<tr>
<td>ProHealth Physicians</td>
<td>Physician group</td>
</tr>
<tr>
<td>Surgical Care Affiliates</td>
<td>Ambulatory Surgery Center</td>
</tr>
<tr>
<td>American Health Network</td>
<td>Physician group</td>
</tr>
<tr>
<td>Reliant Medical Group</td>
<td>Physician group</td>
</tr>
</tbody>
</table>
Impact of Consolidation on Industry

Customer consolidation
- Fewer, larger customers
  - Purchaser bargaining power
  - Price concessions

Industry consolidation
- Fewer larger entities
- Bundled sales agreements
- Role of value based medicine/risk sharing arrangements

New Competitors
- digital health companies
- Civica Rx

Antitrust questions

Industry Update
DRUG PRICING
Drug Pricing

HHS Priorities

1. High list prices for drugs
2. Vertical Integration of Insurers and PBMs
3. Foreign governments free-riding off of American investment in innovation
4. High out-of-pocket costs for consumers

Drug Pricing

List prices
- List prices in ads/Drug dashboard
- Cap on Medicaid inflation-based rebate
- AMP Calculation/incorporate rebates
- Fixed Price Drug Discounts
- Fiduciary Responsibility for PBMs

Negotiation
- Negotiation in Medicare Part B
- Reopen formularies when a sole source generic raises price
- Medicare Part D Protected Classes and Formularies
- Shift Medicare Part B coverage of drugs to Medicare Part D

Competition
- Stop "gaming" that slows Generic Market Entry
- Require sharing samples to develop generic drugs
- Further promotion of the use of biosimilars
- Limit foreign free-riding

Lowering OoP Costs
- Prohibit pharmacy Gag Clauses
- Lower tier for specialty drug if no recent list price increase
- Part D EOB info about price increases, cheaper alternatives
- Real-Time Benefit Check in Medicare Parts B and D
Drug Pricing Initiatives

- Over half of US states have proposed drug pricing laws
- Enacted laws:
  - NY limit on Medicaid drug spending
  - 29 states have passed laws authorizing pharmacies to engage with patients about generic options and alternative pricing models
  - Eight states (CA, VT, NV, CT, ME, OR, LA, TX) have passed drug pricing transparency laws, including justifying price increases
  - ME law encourages production of generics
  - NV and CA have copay caps
  - OK, LA and MA allow state government to negotiate Medicaid pricing

- At the federal level, drug pricing is active
  - New rule: Television ads require list price disclosure. New lawsuit: Amgen, Merck, Eli Lilly sue Trump/CMS declaring rule invalid/unconstitutional
  - Medicare direct negotiations with manufacturers

Drug Pricing Initiatives (cont’d)

- DOJ Generic Drug Price Fixing Probe
  - Beginning in 2014
  - Grand jury located in EDPA
  - Mylan and Perrigo reported raids in 2016-17
  - First charges filed in Dec 2016 against Heritage Pharmaceuticals (individual executive defendants pled guilty in Jan 2017)
  - May 31, 2019 Heritage DPA including $7M criminal penalty and civil damages

- State Antitrust Actions
  - Beginning Dec 2016 (20 states’ AGs) and expanded Nov 2017 (46 states’ AGs)
  - CT v Teva, et al. lawsuit commenced May 2018
  - NH action forthcoming
Industry Update

INNOVATION

Innovation

- 1992 PDUFA
- 2012 GDUFA
- 21st Century Cures Act (2016)
- Former Commissioner Gottlieb’s modernization agenda
- Results = more and faster drug approvals
- Presumably more competition and lower prices
Innovation - Brand

**FDA new innovative medicines approvals by year**

Data compiled: Jan 1, 2019.
Based on U.S. Food & Drug Administration Center for Drug Evaluation and Research reports.
Approvals for 2006 and after include Biologic License Applications for therapeutic biologic products transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research.
Source: S&P Global Market Intelligence.

Innovation – “Orphan” Drugs

**Orphan Percentage**

Source: LEAVITT PARTNERS.
Innovation - Generic

Device Innovation and Breakthrough Products

Major focus of Commissioner

CDRH initiatives
- FIH
- Breakthrough products
- EAP
- Digital health
- Diagnostic test clearances
- Alternative 510(k)
- Precertification

Linkage to reimbursement
- Parallel review challenges
Opioid Epidemic

- DEA collects information regarding the movement of controlled substance ingredients and finished products via its ARCOS system (tracks all CII transactions)
- DEA requires all participants in the supply chain for controlled substances to have “Suspicious Order Monitoring” systems in place
- Orders of controlled substances that deviate in size, pattern or frequency are flagged for investigation
- These rules have largely remained unchanged since the early 1970s
- DEA has for many years promised more specific guidance regarding suspicious order monitoring but has not delivered
### Opioid Epidemic (Cont’d)

- More than 30 states, 2000 cities, counties, tribes and hospitals have filed suit against pharmaceutical companies, wholesalers and pharmacies
- Opioid MDL located in ND Ohio, bellwether cases slated to begin October 2019
- State actions underway:
  - OK: Purdue settled for $270M; Teva settled for $85M; J&J remains (trial began May 28, 2019)
  - ND court on May 10, 2019 dismissed the lawsuit against Purdue (AG will appeal)
  - June 3, CA, HI, ME and DC have sued Purdue
  - June 17, McKesson pays $37M to settle opioid claims (previously, Cardinal ($20M) and ABC ($16M) had settled out)
- **Opioid Litigation Highlights:**
  - Insys (Subsys®) kickback probe - entered into a $225M DPA with DOJ, on June 10 filed for Chapter 11 bankruptcy protection; Seven executives found guilty (2 pled)
  - Purdue (OxyContin®) faces thousands of lawsuits, is considering bankruptcy

### Industry Update

**COURTS – FDA – PRIVACY**
Federal Preemption

- FDCA requires that FDA approve changes to drug labels
- Preemption defense commonly asserted to defeat failure to warn claims
- Plaintiffs seek end-around based on CBE (“newly acquired information”) regulations, PAS, medication guides
- SCT precedent that federal law preempts all failure to warn and design defect claims for brand drugs: *Wyeth v Levine; PLIVA v Mensing; Mutual Pharmaceutical Co. v Bartlett*
- Device preemption is split between PMA and 510(k) devices
  - Broad preemption for PMA products (*Reigel v. Medtronic*)
  - Limited preemption for 510(k) products (*Lohr v. Medtronic*)
- Third Circuit preemption decision in *Fosamax* has resulted in recent SCT decision to vacate and remand (restyled *Merck v Albrecht*)
  - “Clear evidence” that FDA was presented with the warning and declined to add to label (but not via CP)
  - Question of law for judge, not jury
  - Concern about “overwarning”

FDA Enforcement

With one exception, FDA enforcement has been and will be “business as usual”

- FDA continues to enforce against traditional targets
  - Unapproved products such as stem cell products
  - QSR violations
  - Failure to file MDRs/take recall actions
- Continuing caution in off-label promotion area
  - Ongoing 1st Amendment concerns
  - Still waiting for additional FDA guidance
  - FDA/DOJ looking for a “plus” factor
    - False statements
- Don’t expect major reductions in traditional enforcement
- FDA using warning letters to emphasize policy positions
  - Stem cell clinics
  - LDTs (innova warning letter)
Privacy, Data Usage and Consent

- Focus on “big data” requires access to such data
  - Role in RWD/RWE
  - Comparative effectiveness
- “Identification” may not be the only privacy right
  - Right to control information
  - Right to “profit” from data
- HIPAA not all encompassing
  - Other privacy schema
- Consent for “TPA” purposes
- Other data uses may get questioned
  - Recent Michigan case
- Common rule revisions

Cybersecurity

Critical health care area

Substantial Congressional interest
  - potential legislation (PAPHRA?)

HHS challenges
  - organization
  - CMS and related data

FDA initiatives
  - cybersecurity head
  - part of device safety initiative
  - part of SaMD pilot program

Health care issues
  - complexity
  - resource constrained organizations
Industry Trends

Ongoing (and typical) acquisition of startups by established companies
  - Activity will continue
  - Level of med tech investment by VCs
  - Significant HIT/digital health activity
Rise of new competitors
  - Technology companies
  - Dr. Robert Califf
Major merger/acquisitions
  - Medtronic/Covidian
  - Becton Dickinson/Bard
  - Abbott/St. Jude
Market Trends – Horizontal and Vertical Integration

Purchasing power is being horizontally aggregated within hospitals, employers, and practice managers.

Announced Hospital Mergers & Acquisition, 1994 - 2016

The rise in hospital acquisitions is expected to continue in 2018 and reflects a trend to cut costs, improve quality, and expand service offerings.

Hospital Consolidation by HRR

Half of middle-market health care executives plan to merge or acquire businesses in 2018, setting the stage for another big M&A year.

FDA and Advocacy Groups

Many advocacy groups supportive
- Patient groups
- Research advocates

Some opposition
- Public Citizen
- Related supporters

Media attention
- ICIJ articles
- Bleeding Edge
- John Oliver
- Bottle of Lies
- Theranos movies and books
Specific FDA Initiatives

Digital Health

- Interest of Commissioner
- Cross center initiative being led out of CDRH
- FDA fears stifling innovation
- Role of 21st Century Cures provisions and jurisdiction issues
- AI challenges – non-static product
  - Proposed Framework

Opioids

- Enhanced labeling
- Development of abuse deterrent formulations
- Acceleration of abuse treatment drugs and devices
  - Recent device development challenge

Innovative Regulatory Pathways - Precertification

Substantial interest at FDA in precertification processes

- SaMD pilot program
- Diagnostic test reform
- Case for Quality

Precertification may be a true game changer

- Concept is to assessment entity’s systems and performance
- If that meets certain criteria, reduced or eliminated premarket requirements
- Potentially no premarket review of modifications or certain new products

Changes focus from product to system
RWD/RWE

CDER initiatives
- Sentinel efforts

CDRH initiatives
- CDRH wants increase in funding ($40-$50 million)
  - Expect pressure on next user fee negotiation

Public focus is often on role of RWD/RWE in pre-market space
- Potential for faster approval of intended use modifications
  - Depends on off-label use or OUS use

Post-market safety uses of RWD/RWD
- May be larger use
- Key part of device safety initiative

Major role in reimbursement
- Fact of coverage and amount of coverage
- Rise of comparative effectiveness

International Regulatory Efforts

Drugs
Expansion of ICH and related efforts

Devices
Continued or increasing role for IMDRF

Multiple initiatives
- Clinical trials
- Digital health
- Elements of safety and efficacy

International “guidelines” being recognized by FDA
- Software as a medical device (SaMD)

Development of standards by international organizations
- FDA recognition
**Regenerative medicine**

**Major FDA focus**
- Viewed as potential major therapeutic advances
- Jurisdiction issues
  - *Multiple enforcement actions against stem cell clinics*
  - *Similar issues to LDTs – what is a “product” v what is a “service”*

**Effort to accelerate innovation**
- RMAT process
- Multiple products have RMAT designations

**Evolving technology**

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**Patient Engagement**

**Emerging trend**
- Driven by patients

**View of role of patient varies**
- Input into R & D targets
- Patients providing data
- Subjective input into endpoints
- Patients engaged in risk/benefit decisions

**Patient engagement doesn’t neatly fit FDCA**

**Patients as “citizen/scientist”**
- Impact on risk information
**Diagnostic tests – Two Key Activities**

**FDA regulatory**
- Looking to reduce burden/accelerate innovation
- Recent clearances
  - MSK, FoundationOne, 23andMe
- NGS guidances
  - use of public data bases
  - System approaches
- Use of reimbursement as a club

**Legislative efforts**
- VALID
- Bipartisan
- Creates entirely new regulatory system

**1st Amendment/information Exchange**

**Complex legal issues**

**Recent lawsuit against HHS over DTC price advertising**

**Awaiting FDA guidance**
- health economics information exchanges
- Other communication issues

**Limited court activity recently**
- FDA enforcement discretion

**Major FDA challenge**
New Organizational Structures

CDER
- Office of Generic Drugs
- Move of compounding into compliance

CDRH
Office of Product Approval and Compliance (OPAC)
- New organizational construct
- Move from function based organization to product based organization

Combines old ODE and OC functions into product groups
- Same group will handle TPLC – from pre-market to post-market to enforcement
- Goal is to improve communications and information flow
Routine FDA Interactions

Business as usual at FDA
- Product reviews on pace
- Role of pre-sub meetings
- IDE/INDs on pace
- Substantial guidance development activity

New guidance development
- Activist agency – with HHS knowledge
- Push on innovation
- Looking to eliminate non-value added requirements

Pre-market/post-market balance

New technology challenges

FDA and Congress

Currently FDA has a good relationship with Congress
- FDA viewed as rational
- Dr. Gottlieb had very positive relationship with Congress
- Sharpless as acting Commissioner
- FDA alignment with key Congressional concerns
  - Drug pricing
  - Opioids
  - “Right to Try”

Less clear future
FDA and Industry

Industry generally pleased with FDA

- Efforts to reduce regulatory burden are appreciated
- Transparency efforts appreciated
- Most Dr. Gottlieb/Dr. Sharpless initiatives have support
  - Digital health
  - Precertification
  - Drug/device safety initiatives
  - RWD/RWE
- User fee goals generally on track
- Senior center management viewed as supportive and rational
Smooth Sailing on Choppy Waters: Provider Integration in an Uncertain Environment

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Smooth Sailing on Choppy Waters:
Provider Integration in an Uncertain Environment

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**Background**

Hospitals and physicians continue to face the pressure of scale as costs rise and reimbursement continues to decline. With the move from volume to value looming and the corresponding need to have systems in place to be able to take on real risk and to have all players on the same team, for those physicians who have not yet joined forces with hospitals or health systems, the pressure to do so is real, but those practices which remain independent are sometimes fiercely so.

On the other hand, hospitals and health systems have spent a lot of money acquiring physician practices over the last decade and they have not always resulted in the expected increased financial returns. Instead, bottom lines continue to erode, physicians are unhappy with their loss of autonomy and haven’t really realized the reduction in administrative burden going “all in” was supposed to deliver. Over the past 15 years the number of physicians employed by hospitals has nearly doubled.

The surge in hospital employment of physicians has had a few key drivers. Baby-boomer physicians faced challenges in recruiting new physicians. Newer physicians, with loads of student debt have been less willing to take on the entrepreneurial risk of private practice, at a time when those practices were needing to invest in EHRs and other infrastructure to remain competitive. At the same time, imaging reimbursement began its slow decline. Formerly a driver of revenue for specialties like orthopedics, medical oncology and cardiology, those specialties found relief in becoming employed by hospitals and health systems which often pay these specialists more than they receive in professional fee reimbursement for their services. Of course, the ACA increased documentation requirements, increasing overhead and further driving physicians into an employment model. Other market-driven reasons for hospital physician acquisitions range from leveraging payer rates, ensuring the hospital retained specialties that may be hard to recruit to in certain rural and out-state areas as well as the simple exhaustion of health system executives with constant negotiation with local independent physician groups. Direct employment seemed to be the answer to many problems.

As strategic rationale became a moving target, health systems began to realize substantial losses in their employed physician practices. Hospitals and health systems are now realizing the physicians are at the heart of their business, and that an employee mentality does not always produce the results the systems need to remain financially strong.

As a result, both physicians and health systems are increasingly exploring alternatives to a traditional practice sale/acquisition structure. These alternative transaction structures may result in less comprehensive integration than a standard acquisition, but can be more flexible in their duration of delineation of obligations, liabilities and rights among the parties. These alternative structures may still enable the parties to leverage economies of scale inherent in more traditional health system structures and can allow both parties to focus on their areas of expertise thereby taking advantage of the strengths and resources of each partner.
Pre-Transaction Considerations

Before hospitals/health systems and physicians start selecting alternative structures and drawing diagrams, it is imperative that both parties ensure they are aligned on the strategic vision and rationale for a possible transaction as well as ensuring that the parties have cultures and organizational missions that complement each other. There must be long-term value creation for all stakeholders, rather than just short-term success for one or the other party. Measuring true success of any arrangement required to look far beyond the initial perspective of fit and financial return and focus on whether the affiliation ultimately results in compelling value over an extended period of time. If the physician partner is simply interested in maximizing short-term compensation from the health system and the health system is aimed at achieving increased efficiencies and growth, no structure will be viewed as a success by either party. The structure of any given potential partnership should be shaped by the parties shared vision, objectives, principles and parameters for that partnership - all of which will determine the scope and structure of the relationship.

It is equally important that all parties to a potential transaction consider the impact of the transaction on their current business and referral relationships. If the physicians receive a majority of their referrals from a competing health system, will those referrals be put at risk if it is perceived that the group is closer to the competition? Does the health system have a relationship with another oncology group at another hospital site that might be put at risk if it enters into a management agreement with a competitor? Do any of the parties have existing contractual or other business limitations what will impact their ability to partner?

Other institutional issues that should be addressed up front include the involvement of a government entity, for-profit/non-profit structures, ethical and religious directives, impact to employees, existing collective bargaining arrangements, prospective leadership/management, medical staff politics, balance sheet challenges, etc. Identifying these types of institutional issues up front can lead to identifying possible structures which can mitigate and address considerations which could otherwise turn into deal killers.

Finally, a pre-deal structure legal issue review is critical, particularly with regard to antitrust considerations. Because the DOJ’s antitrust division has stated that “antitrust enforcement in healthcare will continue to be a high priority for the Division”, providers must analyze the ability of even a non-merger affiliation transaction, to pass antitrust limitations. Of course alternative structures can serve to mitigate some of the antitrust risks presented by a full-scale acquisition but those structures need to be built knowing whether there is market concentration already and/or whether the proposed transaction could be viewed negatively by the state and federal antitrust enforcement authorities.

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1 Emily Rappleye, Healthcare Antitrust Enforcement Remains a Top Priority for DOJ, BECKER’S HOSPITAL REVIEW (May 20, 2018)
Alternative Transaction Structures

1. Joint Operating Agreement

A “joint operating agreement” is an agreement under which independent organizations transfer control over the assets and activities of the organizations to a central governing authority. The central governing body may be organized as a separate legal entity (tax-exempt organization, LLC, etc.) or may simply be a contractual arrangement created to the terms of the JOA. JOAs have been employed most frequently in healthcare between two formerly unrelated hospitals or health systems.

A JOA achieves many of the same joint venture benefits of full integration without a complete merger or transfer of assets. A JOA, sometimes referred to as a “virtual merger” brings two or more unrelated organizations together to jointly operate certain activities whereby each party of the JOA jointly shares the risks and rewards derived from the shared operations. The key difference between a JOA and a merger is that in a JOA there is no change in ownership of assets. Each party to a JOA retains ownership in their respective assets and agrees to undertake certain obligations contractually within the purview of the JOA. The governing bodies, and their underlying powers, of the JOA parties do not change.

Many organizations find JOA arrangements attractive because it offers many of the advantages of a merger (i.e., economies of scale, access to new markets, broadening service offerings) without a complete loss of a separate legal entity and ownership over its assets. JOAs can be attractive to manage through limitations on asset transfers, or practice limitations, such as those imposed by religiously affiliates systems.

2. Co-Management Structure

There is no single definition of clinical co-management arrangements. Generally, these are agreements under which hospitals/health care systems contract with a physician practice to provide clinical and strategic management services for a specialty line of services, are generally entered into to create strategic alignment between the physicians and system – with shared goals and responsibility for improving quality and decreasing costs. Financial incentives can be aligned along with a higher level of engagement, moving responsibility in some cases, even over the employment and management of related outpatient services, to the physician group. Common specialties using a co-management model include cardiology, oncology, orthopedics, urology, surgery, etc.

If there is more than one non-employed physician group providing services within the system, the co-management structure can be multi-party, that is, the system could enter into an arrangement with multiple groups to achieve the desired service line results.

In the most high functioning co-management structures, a lead physician works in partnership with a system executive (the “Dyad”) and the Dyad takes leadership and responsibility over developing system-wide protocols, recruiting, managing expenses, coordinating unified device and equipment selection – all leading to higher quality and reduced expenses. Responsibilities of the Dyad can include: development of service line structure, operational and capital budgets, recruitment plan and execution, developing and implementing clinical protocols and processes,
physician staffing plans and management, clinical management of related outpatient services, strategic and business planning. A strong physician lead in the Dyad model can lead the other physicians through adapting systems and protocols that are not always the first choice of individual physicians. In a low functioning co-management structure, the physician does not work well in a dyad-environment, letting the hospital executive take administrative and clinical leadership, without that strong physician leadership, the system can end up paying for management services that are not effective.

Co-management arrangements must be “real” – that is – the system and physicians have a shared vision and articulated goals and defined services the group will provide to the system. Of course, co-management arrangements should not have as a goal, paying for referrals, recruiting physicians to use the hospital, encouraging physicians to reduce care or incentivizing physicians to cherry pick patients. There must be strong, contemporaneous documentation of the legitimate purpose for the hospital and physicians entering into the co-management arrangement.

More complex co-management structures create a separate co-management company, such as an LLC, co-owned by the health system and independent physician groups. Some service line structures include a physician steering committee or management committee which includes representation from the various physicians providing services in the service line (system employed, physician group employed, others).

In some co-management structures, the physician group, if it has historically employed and managed clinical staff, can take on that responsibility for hospital outpatient services in the service line to assure that inpatient and outpatient services are aligned and managed cohesively.

Compensation terms are typically structured so that the physician leaders receive a FMV fee for the management services based on the anticipated amount of time that will be expended by the involved physicians. Incentive compensation can be included based upon achieving pre-established goals – patient satisfaction, referring physician satisfaction, quality measures which may include items such as: on-time surgery/procedure starts; lower complication rates; timeliness of drug orders; timeliness of paperwork/medical documentation, mortality/morbidity measures.

A co-management structure can also include a professional services agreement component as well, but the parties must be cautious in ensuring that when all services are “stacked” the hospital/system is still paying FMV in total for the services being provided by the physician group.

3. Professional Services Agreements

An alternative to direct practice acquisition is for a hospital/health system to purchase the services of a physician group through a professional services agreement (PSA). The PSA model enables a hospital or large group practice to enter into professional, management and staffing services arrangement with a separate physician group practice in lieu of direct, permanent acquisition of the practice. The targeted physician practice can participate in the arrangement while preserving its separate legal entity status. The scope of PSA vary widely – a PSA may cover only a narrow band of call coverage for a single specialty, it may include purchasing the
full or part-times services of select physicians, or, at its most robust, may encompass a full-group practice PSA under which the hospital/system purchases all of the professional services of a physician group.

A PSA can include not only professional services, but staffing and support services of the physician group. PSA services are generally limited to inpatient or hospital-based outpatient services, that is, services needed by the hospital or health system. A PSA is challenging to implement for a physician group’s owned outpatient services, but can be used as a bridge to full acquisition or can be used to reduce antitrust risks presented by a full acquisition.

Compensation under a PSA must be set at FMV rates and can be a combination of a base payment, related to the production of the physicians, and incentive payments based on a number of factors which may include personal production, increased quality, patient satisfaction, etc. Fixed compensation in a PSA is rare as it shifts all risk of production to the purchasing hospital/system and creates no incentive for highly productive physicians to maximize compensation. The hospital may also reimburse the practice for the back-office or non-professional services provided by the practice at a pre-determined rate or percentage.

While under a PSA the hospital or system generally bills third party payers for the services, if retaining billing rights is important to the physician group, or as an alternative method to reduce financial outlay of the hospital/system, a PSA can be structured as a “coverage” arrangement. Under a coverage agreement (“CSA”), the physicians are obligated to provide professional services as in a PSA, but compensation is structured so that the hospital pays the physician group only the “gap” between professional collections by the group and a FMV rate for the physician services. Using a coverage arrangement can be most useful in a ramp-up situation as the compensation terms self-correct to ensure that as the practice of a newly recruited physician under the arrangement grows, the hospital’s financial support automatically decreases. For example, if a hospital needs a second cardiovascular surgeon to cover call and ensure quality patient care but the patient volume does not support FMV compensation for an additional surgeon, it can contract with a physician group to recruit and employ the surgeon and compensate the group for the difference between the group’s collections and a FMV rate. The same regulatory concerns and requirements apply and it is important that the hospital/health system makes a determination that it needs the services it is purchasing, i.e., that the arrangement is commercially reasonable. A PSA or CSA should not be used to simply increase the compensation of a physician group which refers to the hospital or health system. There must be legitimate needs and goals of such an arrangement such as improving quality, reducing cost, improving efficiency, etc.

4. Joint Ventures

Physician and hospitals/health systems may also enter into a joint venture, either as a mechanism through which a co-management or other structure discussed above is achieved, or as a means to jointly own a discrete segment of services, such as an ambulatory surgery center. A true joint venture (JV) involves the creation of a separate legal entity, frequently a limited liability company will be used, into which each party provides capital. Ownership of the JV is based on each party’s capitalization of the JV enterprise, where existing businesses or equipment are contributed, third party valuations may be sought to validate the allocation of ownership. JVs
involve negotiation of governance, including the size and composition of the governing body, retained rights by each owner, unwind and termination rights, capital call obligations, non-compete and other practice limitations, etc.

It is critical to perform a regulatory analysis prior to entering into the complex negotiations of a JV to ensure regulatory compliance including antitrust, Stark and AKS as well as provider-based, licensure, COP, etc. is possible considering the types and scope of services desired by the parties.

**Regulatory Landscape**

Any type of arrangement between hospitals and health systems and physician groups can implicate the federal anti-kickback statute, the civil monetary penalty provisions and the Stark law. Antitrust laws and Medicare conditions of participation must also be part of the process for establishing the relationship. State law considerations must also be addressed.

Enforcement of the Stark Law—which prohibits physicians from making certain referrals for designed health services paid for by Medicare if the physician has a prohibited financial relationship with the entity receiving the referral—and the criminal Anti-Kickback Statute (“AKS”) remain top Government priorities. The Department of Justice often employs the False Claims Act to enforce the Stark Law and to recover overpayments paid as a result of improper billing and coding of health care services. A hospital may not seek payment from a federal health care program for a service rendered pursuant to a prohibited referral. The possibility of rewards for whistleblowers\(^2\) as well as the statutory requirement to award treble damages in FCA cases has surely heightened the rigorous enforcement environment.

1. **Anti-Kickback Statute**

The federal Anti-Kickback Statute (2 CFR 1001; 42 CFR 1003) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under “federal health care programs” (as defined in section 1128B(f) of the SSA). The offense is classified as a felony and is punishable by fines and imprisonment.

The AKS statutes’ prohibitions are broad and preclude more than mere payments in exchange for referrals. In particular, under AKS, it is unlawful to request or receive or to offer or pay remuneration for referring an individual to a person for the provision of an item or service covered under a federal health care program, or arranging for or recommending that someone lease, purchase or order a good, facility, service or item covered under a federal health care program. Note that this is a “two-way street”, that is, it is just as illegal to solicit or accept payment for referrals as it is to make such payments. Many times physician groups incorrectly believe that AKS compliance is somehow more important for the health system than for their groups, that is not the case as receiving improper remuneration is also a AKS violation.

\(^2\) 31 U.S.C. § 3730(d)(1) (providing that if the Government proceeds with a *qui tam* action brought by a relator, the relator is entitled to an award of between fifteen and twenty-five percent of the proceeds of the action or a settlement as well as attorneys’ fees); id. § 3730(d)(2) (providing that if the Government does not proceed with the action, the relator is entitled to between a twenty-five and thirty percent award as well as attorneys’ fees).
AKS is an intent based statute, but it does not require actual knowledge of a violation or the specific intent to violate the statute. AKS also does not require agreement between the parties for a statutory violation to occur, the bribe or kickback need only be the quid pro quo for the referral or recommendation. Violations of AKS may result in criminal prosecution and/or exclusion from participation in the Medicare/Medicaid program. In addition, violations can be punished via administrative/CMP in the amounts of up to $50,000 per violation. Treble damages may also be imposed. Violations of the AKS also constitute violations of the Federal Civil False Claims Act.

AKS has a number of safe harbors and full and technical compliance with every element of a safe harbor will remove a relationship or transaction from the risk of civil or criminal prosecution. Unlike the Stark Law, it is not necessary to comply with a regulatory “safe harbor” to the Anti-Kickback Statute. The safe harbors are narrowly drawn and many common business practices are unable to comply with any safe harbors. Where full compliance with an AKS safe harbor is not possible, the parties must endeavor to implement sufficient safeguards to assure AKS compliance. Those may include:

**Fair Market Value.** Ensure financial terms and arrangements are at fair market value and are also considered commercially reasonable through reliance on an independent valuation opinion of all elements of the arrangement. The total compensation to be paid under the arrangement (base plus bonus) must be FMV and commercially reasonable. Inquire as to how long the parties can rely on the opinion and rebase the compensation as recommended by counsel. Generally, an opinion will “cover” an arrangement for two to three years. It is recommended to obtain updated opinions following that if the arrangement is longer term.

**Program Participation.** It can be challenging to include physicians in a new arrangement who do not have a current relationship with the health system. In those cases, care must be taken to assure that payments are not simply for new patient referrals. Where there can be legitimate reasons a system reaches out to a new physician group – quality, coverage needs, special skills, etc. – the presumption could be that the system is using the arrangement to attract referring physicians.

**Program Monitoring.** The parties should monitor admissions to ensure changes in admission patterns are not aimed at cost reduction but at quality of care or other rationale which do not cause regulatory risk.

**Compensation.** The total compensation available under an arrangement should have a self-executing cap to ensure total compensation remains at FMV. If there is a cost-savings (aka gainsharing) component, care must be taken to ensure CMP is not violated.

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3 One federal appellate court has held that if “one purpose” of an arrangement is to induce the referral of business, the law has been violated. *See United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2010). Other courts have held that a “primary purpose” of an arrangement must be to induce the referral of business. *See, U.S. v. Bay State Ambulance and Hospital Rental, Inc.*, 874 F.2d 20, 32 (1st Cir. 1989)

4 *See, e.g., Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)

5 42 CFR 1001.952
Distribution of Compensation. Care must be taken to ensure that any compensation paid by the system is not based on a financial pool which includes DHS and the system should have assurance that the physician groups will distribute compensation in a manner which does not relate to referrals. Distributions on a per capita basis minimizes the incentive of any individual physician to inappropriately reduce or increase services in order to earn an incentive payment.

Identify Metrics with Specificity. The particular actions and metrics that will generate incentive or cost savings payments must be identified in advance and set forth in writing. Those metrics should change each year and should include stretch goals, the achievement of which is unlikely.

2. Stark Law

The Stark Law prohibits physicians from referring Medicare patients to any entity with which the physician (or an immediate family member) has a financial relationship for any designated health service (“DHS”) unless an exception applies. The entity considered to be furnishing the DHS is the person or entity that has performed services that are billed as DHS or the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right of payment for the DHS has been reassigned. Unless an appropriate “exception” can be met, no Medicare payment may be made for DHS that is furnished pursuant to a prohibited referral. The Stark Law also prohibits any entity from billing any individual, third-party payer or other entity for DHS provided pursuant to a prohibited referral. An entity must refund any payment collected for DHS that was furnished under a prohibited referral.

A financial relationship is found (1) where there is a direct or indirect ownership or investment interest in an entity that furnishes DHS or (2) where there is a direct or indirect compensation arrangement with an entity that furnishes DHS. A compensation arrangement is any arrangement, involving direct or indirect remuneration, between a physician (or immediate family member) and an entity providing DHS.

There are numerous exceptions that can be used to protect arrangements from violating the Stark Law. Some exceptions apply only to compensation arrangements, some apply only to ownership arrangements and some apply to both ownership and compensation arrangements. The most common exceptions applicable to these types of hospital/physician arrangements include the fair market value, personal services exception or risk sharing:

Fair Market Value. To qualify for protection under the fair market value exception, an arrangement must satisfy all of the following:

a. Be in writing, signed by the parties, and cover only identifiable items or services, all of which are specified in the arrangement;

b. Specify the timeframe for the arrangement;

c. Specify compensation terms that are set in advance, consistent with fair market

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6 42 CFT 41..354.
value, and not determined in a manner that takes into account the volume or value of referrals, or other business generated by the referring physicians;

d. Specify compensation terms that are commercially reasonable (taking into account the nature and scope of the transaction), further the legitimate business purpose of the parties;

e. Not violate AKS or any federal or state law or regulation governing billing or claims submission; and

f. Not involve services that entail or encourage the counseling or promotion of a business arrangement or other activity that violates a federal or state law.⁷

**Personal Services Exception.** To qualify for protection under the personal services exception, an arrangement must satisfy all of the following elements:

a. Be in writing, signed by the parties, and specify the services covered by the arrangement;

b. The arrangement covers all of the services to be furnished by the physician to the entity;

c. The aggregate services covered do not exceed those that are reasonable and necessary for the legitimate business purpose of the arrangement;

d. The duration is at least one year;

e. The compensation is set in advance, does not exceed FMV, and is not determined in a manner that takes into account the volume or value of referrals or other business generated; and

f. The services to be furnished do not involve a business arrangement that violates any federal or state law.⁸

The risk sharing exception may also be relied upon in the context of certain physician/health system relationships. That exception protects compensation pursuant to a risk-sharing arrangement between an MCO or IP and a physician (either directly or through a subcontractor) for services provided to enrollees of a health plan provided the arrangement does not violate the AKS or laws related to billing and claims submission.⁹

3. **Civil Monetary Penalties**

The Beneficiary Inducement Civil Monetary Penalties statute generally prohibits any person or entity from offering remuneration to a Medicare or Medicaid beneficiary if that remuneration is

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⁷ 42 CFR 411.357(l)
⁸ 42 CFR 411.357(d)
⁹ 42 CFR 411.357(n)
likely to influence the beneficiary's selection of a provider\textsuperscript{10}. OIG amended the definition of remuneration to provide for the following exceptions which went into effect on January 6, 2017\textsuperscript{11} which apply to:

a. Copayment reductions for certain hospital outpatient department services;

b. Certain remuneration that poses a low risk of harm and promotes access to care;

c. Coupons, rebates, or other retailer reward programs that meet specified requirements;

d. Certain remuneration to financially needy individuals; and

e. Copayment waivers for the first fill of generic drugs\textsuperscript{12}.

These changes may be helpful for providers who participate in programs where beneficiary engagement is a central component of achieving positive clinical outcomes.

4. Gainsharing

The concept of “gainsharing” is commonly understood to mean an arrangement between providers, such as a hospital and the physicians who practice at the hospital, that offers participants the opportunity to share in cost savings that result from the efforts of the parties\textsuperscript{13}. Prior to 2015, a provision in the civil monetary penalties provision of the SSA (the “Gainsharing CMP”)\textsuperscript{14} prohibited any hospital from making payments to a physician, either directly or indirectly, as an inducement to reduce or limit care\textsuperscript{15}. Like the Stark Law, this created challenges when the healthcare industry began to shift to a value-based reimbursement model because value-based reimbursement often incentivize collaboration among providers to increase efficiencies and reduce cost. In 2015, section 512(a) of MACRA amended the Gainsharing CMP to prohibit only payments that induced physicians to reduce or limit medically necessary care. This has reduced the risk of implementing gainsharing arrangements at least under the Gainsharing CMP (the Stark Law and Anti-Kickback Statute may still present issues, depending on the specifics of the arrangement). In addition, the OIG has issued numerous advisory opinions over the years that can be used as a roadmap for designing gainsharing arrangements\textsuperscript{16}.

5. Other Compliance Considerations

\textsuperscript{10} 42 U.S.C. § 1320a-7a(5).


The following should also be considered to enhance compliance:

a. **Documentation.** The parties should maintain written documentation of the clinical and operational rationale for the arrangement (e.g., improving quality outcomes, identifying gaps or deficiencies in current services, expanding patient access, improving efficiencies, etc.). The rationales should not be related, directly or indirectly, to referrals.

b. **Metrics.** In establishing the baseline for quality and/or cost savings performance metrics, the parties should review the historical performance of the participating physicians. The baseline should be updated annually to ensure the health system is paying for improvements, not the status quo.

c. **Clinical Support.** The parties should support any quality and/or cost savings performance metrics included in the arrangement with evidence from clinical studies and/or reviews of clinical outcomes. Clinical criteria, not just cost savings, should drive selection of any performance measures. Relying upon credible medical evidence will help ensure that quality and/or cost savings measures do not adversely affect patient care.

d. **Program Oversight.** These types of arrangements should include detailed service line oversight measures. Oversight procedures will help ensure that the performance metrics are neither negatively impacting patient care outcomes nor incentivizing participating physicians to direct more costly or complex patients to other facilities. The parties should consider implementing oversight procedures requiring participating physicians to certify that the receipt of any incentive compensation will not cause them to (i) reduce medically necessary care; (ii) increase referrals; (iii) cherry pick healthy patients; or (iv) inappropriately accelerate patient discharges.

e. **Payments.** Further, the parties should generally avoid compensation approaches which tie payments to: (i) influencing referrals for inpatient or outpatient services; (ii) inappropriate influencing the utilization of any hospital services, including, but not limited to ancillary testing; (iii) incentivizing any efforts that have the potential to limit or reduce medically necessary care through the reduction in costs or otherwise; (iv) prohibiting certain choices by physicians; and (v) providing financial considerations that prevents the exercise of independent professional judgment.
Conclusions

Alternatives to physician group acquisitions can be important tools for hospitals and healthcare systems to achieve increasingly important goals of efficiency and improved quality with groups that are reluctant to be “owned” by a system while also reducing the financial outlay for the hospital or system. A truly shared ownership mentality is critical for physician engagement to offset the losses hospitals have been increasingly experiencing with their employed physician groups. Of course, regulatory compliance is paramount, the foundation of which is ensuring the parties have clearly articulated and documented goals which support the commercial reasonableness of the arrangement, the impact on patient care, improved quality, reduced expenses, etc.
NIST-Facilitated Discussion to Get Your Input on the New Privacy Framework

Presented by:

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Materials prepared by:

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)
Core Functions

Develop the organizational understanding to manage privacy risk for individuals arising from data processing or their interactions with systems, products, or services.

Identify (ID)

Develop and implement appropriate data processing safeguards.

Protect (PR)

Develop and implement appropriate activities to enable organizations or individuals to manage data with sufficient granularity to manage privacy risks.

Control (CT)

Develop and implement appropriate activities to enable organizations and individuals to have a reliable understanding about how data are processed.

Inform (IN)

Develop and implement appropriate activities to take action regarding a privacy breach or event.

Respond (RS)
Table 1: Privacy Framework Function and Category Unique Identifiers

<table>
<thead>
<tr>
<th>Function Unique Identifier</th>
<th>Function</th>
<th>Category Unique Identifier</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID</td>
<td>Identify-P</td>
<td>ID.IM-P</td>
<td>Inventory and Mapping</td>
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<td>ID.BE-P</td>
<td>Business Environment</td>
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<td>ID.GV-P</td>
<td>Governance</td>
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<td>ID.RA-P</td>
<td>Risk Assessment</td>
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<td>ID.RM-P</td>
<td>Risk Management Strategy</td>
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<td>ID.SC-P</td>
<td>Supply Chain Risk Management</td>
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<td>PR</td>
<td>Protect-P</td>
<td>PR.AC-P</td>
<td>Identity Management, Authentication, and Access Control</td>
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<td>PR.AT-P</td>
<td>Awareness and Training</td>
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<td>PR.DS-P</td>
<td>Data Security</td>
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<td>PR.DP-P</td>
<td>Data Protection Processes and Procedures</td>
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<td>PR.MA-P</td>
<td>Maintenance</td>
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<td>PR.PT-P</td>
<td>Protective Technology</td>
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<td>PR.PP-P</td>
<td>Protected Processing</td>
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<td>CT</td>
<td>Control-P</td>
<td>CT.PO-P</td>
<td>Data Management Processes and Procedures</td>
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<td>CT.DM-P</td>
<td>Data Management</td>
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<td>IN</td>
<td>Inform-P</td>
<td>IN.TP-P</td>
<td>Transparency Processes and Procedures</td>
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<td>IN.AW-P</td>
<td>Data Processing Awareness</td>
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<td>RS</td>
<td>Respond-P</td>
<td>RS.RP-P</td>
<td>Response Planning</td>
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<td>RS.CO-P</td>
<td>Communications</td>
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<td>RS.AN-P</td>
<td>Analysis</td>
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<td>RS.MI-P</td>
<td>Mitigation</td>
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<td>RS.IM-P</td>
<td>Improvements</td>
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<td>RS.RE-P</td>
<td>Redress</td>
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<tr>
<td>IDENTIFY-P (ID)</td>
<td>Inventory and Mapping (ID.IM-P): Data processing and individuals’ interactions with systems, products, or services are understood and inform the management of privacy risk.</td>
<td>ID.IM-P1: Systems/products/services that process data, or with which individuals are interacting, are inventoried.</td>
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<td>ID.IM-P2: The owners or operators of systems/products/services that process data, or with which individuals are interacting, are identified.</td>
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<td>ID.IM-P3: Data elements that systems/products/services are processing are inventoried.</td>
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<td>ID.IM-P4: Data actions are identified.</td>
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<td>ID.IM-P5: The data processing environment is identified (e.g., internal, cloud).</td>
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<td>ID.IM-P6: Data processing is mapped, illustrating the processing of data elements by system components and their owner/operators, and interactions of individuals and organizations with the systems/products/services.</td>
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<tr>
<td>Business Environment (ID.BE-P): The organization’s mission, objectives, stakeholders, and activities are understood and prioritized; this information is used to inform privacy roles, responsibilities, and risk management decisions.</td>
<td>ID.BE-P1: The organization’s role in the supply chain is identified and communicated.</td>
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<td>ID.BE-P2: Priorities for organizational mission, objectives, and activities are established and communicated.</td>
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<td>ID.BE-P3: Systems/products/services that support organizational priorities are identified and key functional requirements communicated.</td>
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<td>Governance (ID.GV-P): The policies, procedures, and processes to manage and monitor the organization’s regulatory, legal, risk, environmental, and operational requirements are understood and inform the management of privacy risk.</td>
<td>ID.GV-P1: Organizational privacy policies are established and communicated.</td>
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<td>ID.GV-P2: Processes to instill organizational privacy values within system/product/service development operations are in place.</td>
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<td>ID.GV-P3: Privacy roles and responsibilities for the entire workforce are established.</td>
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<td>ID.GV-P4:</td>
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<td>Privacy roles and responsibilities are coordinated and aligned with third-party stakeholders (e.g., suppliers, customers, partners).</td>
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<td>ID.GV-P5:</td>
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<td>Legal, regulatory, and contractual requirements regarding privacy are understood and managed.</td>
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<td>ID.GV-P6:</td>
<td></td>
<td>Governance and risk management processes address privacy risks.</td>
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</table>

**Risk Assessment (ID.RA-P):** The organization understands the privacy risks to individuals and how such privacy risks may create secondary impacts on organizational operations (including mission, functions, reputation, or workforce culture).

| ID.RA-P1: | The purposes for the data actions are identified. |
| ID.RA-P2: | Contextual factors related to the systems/products/services and the data actions are identified (e.g., individuals’ privacy interests and perceptions, demographics, data sensitivity). |
| ID.RA-P3: | Potential problematic data actions and associated problems are identified. |
| ID.RA-P4: | Problematic data actions, likelihoods, and impacts are used to determine and prioritize risk. |
| ID.RA-P5: | Risk responses are identified and prioritized. |
| ID.RA-P6: | Risk is re-evaluated as data processing or individuals’ interactions with systems/products/services change. |

**Risk Management Strategy (ID.RM-P):** The organization’s priorities, constraints, risk tolerances, and assumptions are established and used to support operational risk decisions.

| ID.RM-P1: | Risk management processes are established, managed, and agreed to by organizational stakeholders. |
| ID.RM-P2: | Organizational risk tolerance is determined and clearly expressed. |
| ID.RM-P3: | The organization’s determination of risk tolerance is informed by its role in the ecosystem. |

**Supply Chain Risk Management (ID.SC-P):** The organization’s priorities, constraints, risk tolerances, and assumptions are established

<p>| ID.SC-P1: | Supply chain risk management processes are identified, established, assessed, managed, and agreed to by organizational stakeholders. |</p>
<table>
<thead>
<tr>
<th>Function</th>
<th>Category</th>
<th>Subcategory</th>
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</thead>
<tbody>
<tr>
<td>PROTECT-P (PR)</td>
<td>Identity Management, Authentication, and Access Control (PR.AC-P): Access to data and devices is limited to authorized individuals, processes, and devices, and is managed consistent with the assessed risk of unauthorized access.</td>
<td>ID.SC-P2: Service providers/suppliers/third-party partners of data processing systems, products, and services are identified, prioritized, and assessed using a supply chain risk assessment process.</td>
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<td>ID.SC-P3: Contracts with service providers/suppliers/third-party partners are used to implement appropriate measures designed to meet the objectives of an organization’s privacy program and supply chain risk management plan.</td>
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<td>ID.SC-P4: Service providers/suppliers/third-party partners are routinely assessed using audits, test results, or other forms of evaluations to confirm they are meeting their contractual obligations.</td>
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<td>ID.SC-P5: Response planning and testing are conducted with service providers/suppliers/third-party providers.</td>
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<td>PR.AC-P1: Identities and credentials are issued, managed, verified, revoked, and audited for authorized individuals, processes, and devices.</td>
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<td>PR.AC-P2: Physical access to data and devices is managed.</td>
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<td>PR.AC-P3: Remote access is managed.</td>
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<td>PR.AC-P4: Access permissions and authorizations are managed, incorporating the principles of least privilege and separation of duties.</td>
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<td>PR.AC-P5: Network integrity is protected (e.g., network segregation, network segmentation).</td>
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<td>PR.AC-P6: Individuals and devices are proofed and bound to credentials, and authenticated commensurate with the risk of the transaction (e.g., individuals’ security and privacy risks and other organizational risks).</td>
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<td>PR.AC-P7: Attribute references are used instead of attribute values.</td>
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<td>PR.AT-P1: All users are informed and trained.</td>
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<tr>
<td><strong>Awareness and Training (PR.AT-P):</strong> The organization’s personnel and partners are provided privacy awareness education and are trained to perform their privacy-related duties and responsibilities consistent with related policies, procedures, and agreements.</td>
<td>PR.AT-P2: Privileged users understand their roles and responsibilities.</td>
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<td>PR.AT-P3: Third-party stakeholders (e.g., service providers, customers, partners) understand their roles and responsibilities.</td>
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<td></td>
<td>PR.AT-P4: Senior executives understand their roles and responsibilities.</td>
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<td>PR.AT-P5: Privacy personnel understand their roles and responsibilities.</td>
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<tr>
<td><strong>Data Security (PR.DS-P):</strong> Data are managed consistent with the organization’s risk strategy to protect individuals’ privacy and maintain data confidentiality, integrity, and availability.</td>
<td>PR.DS-P1: Data-at-rest is protected.</td>
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<td>PR.DS-P2: Data-in-transit is protected.</td>
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<td>PR.DS-P3: Systems/products/services and associated data are formally managed throughout removal, transfers, and disposition.</td>
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<td>PR.DS-P4: Adequate capacity to ensure availability is maintained.</td>
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<td>PR.DS-P5: Protections against data leaks are implemented.</td>
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<td>PR.DS-P6: Integrity checking mechanisms are used to verify software, firmware, and information integrity.</td>
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<td>PR.DS-P7: The development and testing environment(s) are separate from the production environment.</td>
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<td>PR.DS-P8: Integrity checking mechanisms are used to verify hardware integrity.</td>
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<tr>
<td><strong>Data Protection Processes and Procedures (PR.DP-P):</strong> Security and privacy policies (that address purpose, scope, roles, responsibilities, management commitment, and coordination among organizational entities), processes, and procedures are maintained and used to manage the protection of data.</td>
<td>PR.DP-P1: A baseline configuration of security and privacy controls is created and maintained.</td>
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<td>PR.DP-P2: A system development life cycle to manage systems and an information life cycle to manage data are aligned and implemented.</td>
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<td>PR.DP-P3: Configuration change control processes are in place.</td>
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<td>PR.DP-P4: Backups of information are conducted, maintained, and tested.</td>
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<td>PR.DP-P5: Policy and regulations regarding the physical operating environment for organizational assets are met.</td>
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<td>PR.DP-P6:</td>
<td>Data are destroyed according to policy.</td>
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<td>PR.DP-P7:</td>
<td>Protection processes are improved.</td>
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<td>PR.DP-P8:</td>
<td>Effectiveness of protection technologies is shared.</td>
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<td>PR.DP-P9:</td>
<td>Response plans (Incident Response and Business Continuity) and recovery plans (Incident Recovery and Disaster Recovery) are in place and managed.</td>
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<td>PR.DP-P10:</td>
<td>Response and recovery plans are tested.</td>
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<td>PR.DP-P11:</td>
<td>Privacy procedures are included in human resources practices (e.g., deprovisioning, personnel screening).</td>
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<td>PR.DP-P12:</td>
<td>A vulnerability management plan is developed and implemented.</td>
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<td>Maintenance (PR.MA-P):</td>
<td>System maintenance and repairs are performed consistent with policies and procedures.</td>
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<td>PR.MA-P1:</td>
<td>Maintenance and repair of organizational assets are performed and logged, with approved and controlled tools.</td>
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<td>PR.MA-P2:</td>
<td>Remote maintenance of organizational assets is approved, logged, and performed in a manner that prevents unauthorized access.</td>
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<td>Protective Technology (PR.PT-P):</td>
<td>Technical security solutions are managed to ensure the security and resilience of systems/products/services and associated data, consistent with related policies, procedures, and agreements.</td>
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<td>PR.PT-P1:</td>
<td>Audit/log records are determined, documented, implemented, and reviewed in accordance with policy and incorporating the principle of data minimization.</td>
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<td>PR.PT-P2:</td>
<td>Removable media is protected and its use restricted according to policy.</td>
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<td>PR.PT-P3:</td>
<td>The principle of least functionality is incorporated by configuring systems to provide only essential capabilities.</td>
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<td>PR.PT-P4:</td>
<td>Communications and control networks are protected.</td>
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<td>PR.PT-P5:</td>
<td>Mechanisms (e.g., failsafe, load balancing, hot swap) are implemented to achieve resilience requirements in normal and adverse situations.</td>
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<td>Protected Processing (PR.PP-P):</td>
<td>Technical data processing solutions increase disassociability consistent with related policies, procedures,</td>
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<td>PR.PP-P1:</td>
<td>Data are processed in an unobservable or unlinkable manner.</td>
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<td>PR.PP-P2:</td>
<td>Data are processed to limit the identification of individuals.</td>
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<tr>
<td>and agreements and the organization’s risk strategy to protect individuals’ privacy.</td>
<td>PR.PP</td>
<td>PR.PP-P3: Data are processed to restrict the formulation of inferences about individuals’ behavior or activities.</td>
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<td>PR.PP-P4: Data are processed through a distributed system architecture.</td>
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<td>PR.PP-P5: Data are processed on local devices.</td>
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<tr>
<td>CONTROL-P (CT)</td>
<td>Data Management Processes and Procedures (CT.PO-P): Policies (that address purpose, scope, roles, responsibilities, management commitment, and coordination among organizational entities), processes, and procedures are maintained and used to manage data consistent with the organization’s risk strategy to protect individuals’ privacy.</td>
<td>CT.PO</td>
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<td>CT.PO-P2: Processes for enabling data review, transmission/disclosure, alteration, or deletion are in place.</td>
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<td>CT.PO-P3: Processes and procedures for enabling individuals’ data processing preferences and requests (e.g., individual participation) are in place.</td>
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<td>Data Management (CT.DM-P): Data are managed consistent with the organization’s risk strategy to protect individuals’ privacy and increase manageability.</td>
<td>CT.DM</td>
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<td>CT.DM-P2: Individuals’ authorization for the data action is obtained.</td>
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<td>CT.DM-P3: Data elements can be accessed for review.</td>
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<td></td>
<td>CT.DM-P4: Data elements can be accessed for transmission or disclosure.</td>
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<td>CT.DM-P5: Data elements can be accessed for alteration.</td>
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<td>CT.DM-P6: Data elements can be accessed for deletion.</td>
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<td>CT.DM-P7: Metadata containing processing permissions and related data values are transmitted with data elements.</td>
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<td>CT.DM-P8: Processing permissions are transmitted using standardized formats.</td>
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<tr>
<td>INFORM-P (IN)</td>
<td>Transparency Processes and Procedures (IN.TP-P): Policies (that address purpose, scope, roles, responsibilities, management</td>
<td>IN.TP</td>
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<td>Function</td>
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<td>commitment, and coordination among organizational entities, processes, and procedures are maintained and used to increase transparency of the organization’s data processing practices.</td>
<td><strong>Data Processing Awareness (IN.AW-P):</strong> Individuals and organizations have an awareness of data processing practices, and processes and procedures are used and maintained to increase predictability consistent with the organization’s risk strategy to protect individuals’ privacy.</td>
<td>IN.TP-P2: Processes for communicating data processing purposes are in place.</td>
</tr>
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<td><strong>Response Planning (RS.RP-P):</strong> Response processes and procedures are executed and maintained to ensure response to privacy breaches and events.</td>
<td>IN.AW-P1: Records of data disclosures are maintained and can be shared.</td>
</tr>
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<td><strong>Communications (RS.CO-P):</strong> Response activities are coordinated with internal and external stakeholders (e.g., external support from law enforcement agencies).</td>
<td>IN.AW-P2: Individuals are informed about data processing practices.</td>
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<td>IN.AW-P3: System/product/service design enhances data processing visibility.</td>
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<td>IN.AW-P4: Data sources are informed of data deletion and correction.</td>
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<td>IN.AW-P5: Individuals are informed when data are corrected or deleted.</td>
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<td>IN.AW-P6: Data provenance is maintained and can be shared.</td>
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<td>IN.AW-P7: Data analytic inputs and outputs are understood and evaluated for bias.</td>
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<tr>
<td>RESPOND-P (RS)</td>
<td></td>
<td>RS.RP-P1: Response plan is executed during or after a privacy breach or event.</td>
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<td>RS.CO-P1: Personnel know their roles and order of operations when a response is needed.</td>
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<td>RS.CO-P2: Privacy breaches and events are reported consistent with established criteria.</td>
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<td>RS.CO-P3: Information is shared consistent with response plans.</td>
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<td></td>
<td>RS.CO-P4: Coordination with stakeholders occurs consistent with response plans.</td>
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<td>RS.CO-P5: Data for voluntary information sharing is restricted to what is necessary for understanding the privacy breach or event.</td>
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<td>Function</td>
<td>Category</td>
<td>Subcategory</td>
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<tr>
<td>Analysis</td>
<td>RS.AN-P</td>
<td><strong>RS.AN-P1</strong>: Notifications from detection systems or processes are investigated.</td>
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<td><strong>RS.AN-P2</strong>: The impact of the privacy breach or event on individuals, the organization, and the ecosystem is understood.</td>
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<td><strong>RS.AN-P3</strong>: Forensics are performed.</td>
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<td><strong>RS.AN-P4</strong>: Privacy breaches and events are categorized consistent with response plan.</td>
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<td><strong>RS.AN-P5</strong>: Processes are established to receive, analyze, and respond to problematic data actions disclosed to the organization from internal and external sources (e.g., internal testing, privacy researchers).</td>
</tr>
<tr>
<td>Mitigation</td>
<td>RS.MI-P</td>
<td><strong>RS.MI-P1</strong>: Privacy breaches and events are contained.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>RS.MI-P2</strong>: Privacy breaches and events are mitigated.</td>
</tr>
<tr>
<td></td>
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<td><strong>RS.MI-P3</strong>: Newly identified problematic data actions are mitigated or documented as accepted risks.</td>
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<tr>
<td>Improvements</td>
<td>RS.IM-P</td>
<td><strong>RS.IM-P1</strong>: Policies and processes incorporate lessons learned.</td>
</tr>
<tr>
<td>Redress</td>
<td>RS.RE-P</td>
<td><strong>RS.RE-P1</strong>: Processes for receiving and responding to complaints, concerns, and questions from individuals about organizational privacy practices are in place.</td>
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<tr>
<td></td>
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<td><strong>RS.RE-P2</strong>: Individuals are provided with mitigation mechanisms.</td>
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Tracking the Elusive Unicorn: How to find the Win-Win-Win in Value-Based Contracting

Presented and materials prepared by:

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The Elusive Win-Win-Win:
Aligning the interests of Patients, Providers, and Payers

By: Santo Cruz

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2) VALUE BASED CONTRACT TYPES..................................................................................................... 2
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4) CONCLUSION........................................................................................................................................ 6
1) INTRODUCTION

VBCs come in several forms and go by many names. However, each present similar challenges and benefits. The goal of this outline is not to recite every VBC model and include its programmatic detail. Rather, the goal here is to ensure that key questions are asked, important considerations are appreciated, and critical conversations are had, prior to entering a VBC.

There are many drivers creating the need to explore cost containment strategies like value-based-contracting (VBC) for healthcare. Here, we will unpack just one.

We are currently in the middle of an unprecedented demographic shift in Minnesota.

From 2010-2030, approximately 640,000 Minnesotans will turn 65 years old, by contrast, from 1950 to 2010, only 416,000 Minnesotans turned 65.¹ The Minnesota State Demographer projects that by 2035, for the first time in state history, there will be more 65+ Minnesotans than 18-and-younger Minnesotans.²

As our state ages, the demand for healthcare services will increase. This demand, combined with the current trend in healthcare costs, has created projections hard to imagine as economically or politically viable. In 2016, Minnesota’s public and private sectors spent a combined 47.1 billion dollars on healthcare.³ However, in just seven years from now, based on current trends and nearly certain demographic shifts, the spending trend projections are a staggering 94.2 billion dollars in the year 2026.⁴

In the face of these projections, payers and providers must find the tools necessary to ensure we, the patients, are not priced out of the market. While no single strategy can meet the multiple challenges we face, VBC is among the tools needed.

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¹ Minnesota State Demographic Center slide presentation to the Bloomington Rotary: Slide 7 Demographic Change in Minnesota by Susan Brower, Minnesota State Demographer; U.S. Census Bureau Statistics
³ Minnesota Department of Health: Minnesota Health Care Spending: 2015 and 2016 Estimates and Ten-Year Projections, REPORT TO THE MINNESOTA LEGISLATURE February 2019
⁴ Id
2) VALUE BASED CONTRACT TYPES

VBCs come from two different sectors: public and private. The public sector can be further subdivided by which level of government is administering the program.

On the federal level, the Center for Medicare and Medicaid Services (CMS) administers the Shared Savings Program (MSSP) for Accountable Care Organizations (ACO) which allows multiple, even previously unaffiliated, healthcare providers to enter collectively into a VBC for an attributed Medicare population. Previously unaffiliated healthcare providers must either join an existing or create a new legal entity for governance of the ACO to meet the requirements of CMS. There are multiple tracks within the MSSP program, for more details, please visit: https://www.naacos.com/assets/docs/news/revisedsummaryaco-comparisonchart.pdf.

Similarly, the Minnesota Department of Human Services administers the Integrated Health Partnership (IHP) program. The IHP is in many ways like ACO for an attributed Medical Assistance (MA) (Medicaid) and MinnesotaCare population. These enrollees may be in either Fee-For-Service (FFS) or within a Managed Care Organization (MCO). For more detailed information please visit: https://mn.gov/dhs/partners-and-providers/news-initiatives-reports-workgroups/minnesota-health-care-programs/integrated-health-partnerships/.

While private sector VBCs are less transparent than their public sector counterparts, the general features are the same. All VBCs seek to incentivize increases in quality while capping or reducing costs for a attributed population.

3) KEY QUESTIONS AND CONSIDERATIONS PRIOR TO ENTERING INTO A VBC:

i) **Attribution**: The process of identifying the population the VBC will cover. The attribution methodology varies greatly between the MSSP, IHP program, and private sector. There are also significant variations within each of the programs themselves, depending on which track or type you are pursuing. There are too many variations to recite here, however there are several key factors for your client to consider regarding attribution:

(1) **What data is available for this population?**

(a) In general, attribution is weighted in favor of primary care services. This is in large part due to the value proposition of low-cost preventative services and early detection of treatable conditions, thereby reduction acuity and costly
inpatient stays and emergency services. Therefore, VBCs are primarily about preventing the preventable, treating early that which cannot be prevented, and coordinating care well enough to know the difference. These are data-driven considerations, without good data and good analytics, there will be no way to know if the risk is being managed.

(2) How will the data be shared, protected, and reported?

(a) It is important to understand who gets to see the data and when, what privacy laws apply to that data and what obligations your client or organization has to collect and report back to the other party its own data.

(3) Will there be a risk adjustment or risk score attached to the attributed population and will the inherent risk of the population be subject to ongoing monitoring and scoring?

(a) These scores or adjustments can impact the payments received or the expectations of the value proposition associated for the population. For example, DHS builds in an increase in the Per-Member-Per-Month (PMPM) payment tied to the risks factor association with the attributed population. 5

(4) Does the organization have a strategy to reach-out to the attributed population?

(a) VBCs are built predicated on vertical and horizontal communication strategies. Vertical communications strategies engage the enrollee; horizontal communication strategies engage the care team for the benefit of that enrollee.

ii) Risk: the element of uncertainty and probability in your VBC. Like attribution models, risk models vary widely among different VBC programs.

(1) How is risk tied to the reimbursement model within the VBC?

(a) This is a question aimed at understanding the relationship between the uncertainty built into the anticipated outcomes of the contract and whether your organization believes it has the capacity to influence those outcomes via some type of strategy or planning. Some VBCs have no downside risk and are

5 Integrated Health Partnerships 2019 Request for Proposal Overview, Page 18, Mathew Spaan | Manager, Care Delivery & Payment Reform mathew.spaan@state.mn.us July 9, 2018
designed to be more of an on-ramp into VBCs. These VBC typically reward upside metrics while discounting or disregarding downside risk. CMS’s original “Track 1” is a good example of this model that is meant to incentivize increased risk capacity.

(2) How will the organization communicate the risk to care team or network of care providers?

(a) There are at least two extreme approaches on how this communication and conversation can happen. One is the approach that believes the organization has been too siloed for too long and that taking on risk will drive the need and sense of urgency to breakdown those silos and communicate horizontally much better. The other is the approach that seeks to first build the perfect horizontal communication strategy, implement that strategy, monitor it, improve it and then consider taking on risk. Both extreme approaches fail to live within the dynamic reality of any organization and the multiple personalities that live within it. A hybrid approach is usually much more realistic and much more effective. Consider including the following infrastructure into your horizontal communication strategy:

1. A core team pulled from the key practice areas that are most closely tied to the quality metrics.

2. A venue of regular exchange of information, both formal and informal, that can lift-up ideas for consideration from the core team, as well as, disseminate key data analytics that can provide context for the care teams.

3. A support network that will seek the resources necessary to implement good ideas, as well as, advocate and influence the removal of barriers to increased coordination.

4. As close as possible to real-time identification of opportunities for improvement.

(3) Is the organization prepared financially to take the risk and if not, are there steps or products available that can mitigate the financial risk?

(a) This assessment can be taken in three stages. The first is more an internal inventory of available resources. The second is gaining a deep understanding how, and at what interval, reimbursement within the VBC will make its way to
your organization. Some VBCs have quarterly payments along the way with annual look-backs, others make prospective payment within a full capitation model for total cost of care (TCOC). No matter the mechanism, the language of the contract must not only be clear, but also clearly understood by the organization in order to move to stage three. Stage three is setting aside the reserves needed and acquiring the necessary financial risk mitigation plan or products.

(4) Can my organization get out of the VBC if, after a prescribed term, the risk profile turns out to be too high?

(a) How and when your organization can terminate the contract is an important conversation to have with all the parties to the contract. When one party makes a written assurance about the risk profile, there ought to be a corresponding mechanism within the contract to address bad data, bad assumptions, and bad luck. A VBC cannot address all contingencies, but it ought to have a process built-in to account for important changes. Some offer contract amendments at a certain interval; these amendments are important opportunities to reassess the risks being taken.

iii) Value and Quality: the ultimate goal of a VBC.

(1) Who gets to define Value and Quality and how will they be measured?

(a) Patient satisfaction scores are an example of the patient getting to define value and quality, with the measurement tool coming from the provider. Hospital readmission statistics are an example of the payer defining quality and value, while the measurement might be a matter of negotiation in the contract. How many readmissions can be tolerated in a VBC could be a function of the risk profile of the attributed population. These considerations are often inter-dependent and dynamic. Therefore, the terms of the VBC ought to be as well.

(2) How many metrics will be measured?

(a) If your organization is in multiple VBCs is it likely they track different quality metrics, this can weigh-down the capacity of the organization to focus on process improvement and tie-up resources measuring the same process from multiple angles.
(3) How often will the metrics be measured?

(a) As VBC branch our into addressing health disparities that result from social determinates, it is less and less likely key data points will be easily pulled from your Electronic Medical Records (EMR). Thus, as greater focus moves outside the four walls of traditional healthcare delivery and into the community and population health, these measurements can present a significant challenge.

(4) How often and what time of year will the reports on quality measurement be due?

(a) Often within an organization, the same individuals are tasked with responding to audits, providing internal reports, and compliance with external reporting. It is important to have insight into the capacity of the internal team regarding the interval at which they will need to be able to produce reports.

(5) Will your organization get an opportunity to see the performance of other organizations similarly situated?

(a) The VBC doesn’t exists within a vacuum and there is often an incentive on the part of the payer to share key learnings from other successful VBCs to assist your organization in its own journey. These tips and consultations should be sought early and accommodated within your VBC to ensure organization can learn and benefit from other VBCs.

4) CONCLUSION

This is certainly not an exhaustive list and there are many resources available to you and your organization. Here are just a few:

https://www.naacos.com/

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/

https://edocs.dhs.state.mn.us/lfserver/Public/DHS-3780-ENG
Tracking the Elusive Unicorn:
How to find the Win-Win-Win in Value-Based Contracting

By: Jesse A. Berg, J.D., M.P.H.

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III. 2018 Stark Law Updates

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   A. The Stark Law directly impedes VBP’s.
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   D. The “Volume or Value of Referrals” Standard.
   F. Stark Law’s Definition of “Fair Market Value”.
   G. Many Stark Law Exceptions also Require that an Arrangement be “Commercially Reasonable”.
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   I. Commentary in Stark Law that Supports Use of Exceptions in Value Based Arrangements.

V. Potential Solutions for Squaring Incentives of Value-Based Programs with Regulatory Restrictions in Stark Law and AKS
   A. A Regulatory or Legislative Fix?
   B. U.S. Senate is Reviewing the Issue.
   C. 2018 Request for Information.
I. **What is a “value based program”?**

At their core, value based programs (“VBPs”) are alternative payment models designed to incentivize behavior leading to better outcomes. VBP incentives are typically tied to quality measurements and seek to reward providers for efficiency and effectiveness.

A. **Overview of Delivery System and Payment Transformation.**

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<thead>
<tr>
<th>Historical State —</th>
<th>Future State —</th>
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<tr>
<td>Producer-Centered</td>
<td>People-Centered</td>
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<td>Volume Driven</td>
<td>Outcomes Driven</td>
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<td>Unsustainable</td>
<td>Sustainable</td>
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<tr>
<td>Fragmented Care</td>
<td>Coordinated Care</td>
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<tr>
<td>FFS Payment Systems</td>
<td>New Payment Systems and other Policies</td>
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- Value-based purchasing
- ACOs, Shared Savings
- Episode-based payments
- Medical Homes and care management
- Data Transparency

B. **Value Based Models and Programs.**

a. There are three essential components of Value Based Models: a measure of patient benefit through a health care service; quantitative information regarding the cost of the service; and a financial arrangement where a plan, provider, or other party commits to deliver a specific patient benefit or a group of services at a target price.

b. Traditional fee-for-services reimbursement rewarded services based on quantity. Under VBP, healthcare providers are incentivized to provide more coordinated, appropriate, and effective care. Value based programs reward providers for using evidence-based medicine, engaging patients, upgrading health IT, and using data analytics. The use of financial incentives to encourage providers to realize positive outcomes is of obvious interest. However, as discussed more below, doing so runs the risk of violating various federal laws broadly grouped under the concept of “fraud and abuse”.

c. The Centers for Medicare & Medicaid Services’ (“CMS”) use of VBPs have a long history. Early versions include:
i. 1991—Medicare Participating Heart Bypass Center Demo; and
ii. 1993—Medicare Cataract Surgery Alternate Payment Demo.

d. Most recently, there have been a flurry of VBP-type programs adopted under various pieces of federal legislation. This includes Medicare Improvements for Patients and Providers Act (“MIPAA”, 2008); Affordable Care Act (“ACA”, 2010); and Protecting Access to Medicare Act (“PAMA”, 2014). Programs developed pursuant to these statutes have included the following:
   i. Hospital Value-Based Purchasing Program (ACA, 2012);
   ii. Hospital Readmission Reduction Program (ACA, 2012);
   iii. Hospital Acquired Conditions Program (ACA, 2013);
   iv. End-Stage Renal Disease Quality Incentive Program (MIPPA, 2012);
   v. Skilled Nursing Facility Value-Based Purchasing Program (PAMA, 2014);
   vi. Value-Modifier or Physician Value Based Modifier (ACA, 2015);
   and

e. In addition, 2015’s Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”) expanded the scope of VBP reimbursement under Medicare Part B through:
   i. Merit-Based Incentive Payment System (MIPS); and
   ii. Advanced Payment Models (APMs).

C. Overview of Payment Formats

a. Fee for Service. This form of reimbursement historically involved no link to quality. Instead, payments are based on the volume of services and not linked to quality or efficiency. Medicare Part B historically was entirely fee-for-service. A majority of Medicare payments now are linked (in least in part) to quality. Medicaid treatment of fee-for-services varies from state to state.

b. Fee for Service + Link to Quality. This means that at least a portion of payments vary based on the quality or efficiency of health care delivery. Examples of existing programs in this area include hospital value-based purchasing, MACRA/MIPS, hospital readmissions; and CMS’ hospital acquired conditions program.

c. Alternative Payment Models Based on Fee-for-Service Architecture. In these models, some portion of the payment is linked to the effective management of a population or an episode of care. Payments are still triggered by delivery of services, but opportunities exist for shared savings or 2-sided risk (reward or penalty depending on results). Examples of Medicare programs that fall into this category include Accountable Care Organizations, Medical Homes and the Bundled Payments for Care Improvements program.
d. **Population-Based Payment.** In these models, payment is not directly triggered by service delivery. This means volume is not linked to payment. Rather, clinicians and provider organizations are paid and responsible for the care of a beneficiary over a long period.

D. **Where are Things Headed?**

a. Shift from Fee-for-Service in Medicare appears to be permanent.
   i. Early CMS Goal: 30% of Medicare payments tied to quality or value through alternative payment models or population based payment by the end of 2016 and 50% by the end of 2018.
   ii. More aggressive CMS Goal: 85% of Medicare fee-for-service payments are tied to quality or value (fee-for-service, link to quality; alternative payment models or population based payment) by the end of 2016, and 90% by the end of 2018.

E. **MACRA-MIPS.**

a. Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created the Merit-Based Incentive Payment System (“MIPS”):
   i. MIPS allows physicians to earn adjusted payments based on evidence-based and practice-specific quality data.
   ii. Physicians report on quality, improvement activities, advancing care information, and costs.
   iii. CMS adjusts reimbursement rates beginning January 1, 2019 based on data from the previous reporting year.
   iv. The clinician’s reimbursement rate may vary between -4% and +4% depending on their reported metrics.
   v. Each year, the percentage by which a clinicians’ reimbursement rate may vary increases.

F. **MACRA—APMs.**

a. MACRA also created Advanced Payment Models (“APMs”)
b. Advanced APMs may earn 5% incentive payment by improving patient care and taking on more risk through the Advanced APM. By 2017, the following Advanced APM Models were available:
   i. Comprehensive ESRD Care (Two-Sided Risk);
   ii. Comprehensive Primary Care Plus (CPC+);
   iii. Next Generation ACO Model;
   iv. Shared Savings Program – Track 2;
   v. Shared Savings Program – Track 3;
   vi. Oncology Care Model (OCM) (Two-Sided Risk); and
   vii. Comprehensive Care for Joint Replacement (CJR) Payment Model (Track 1-CEHRT).
G. **Other Value-Based Programs.** Other value-Based Programs in existence or recently in use (Center for Medicare and Medicaid Innovation or Otherwise):

a. Accountable Care Organizations (ACOs):
   i. Medicare Shared Savings Program;
   ii. Pioneer ACO Model; and
   iii. Advance Payment ACO Model.

b. Primary Care Transformation:
   i. Comprehensive Primary Care Initiative (CPC);
   ii. Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration;
   iii. Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration;
   iv. Independence at Home Demonstration; and
   v. Graduate Nurse Education Demonstration.

c. Bundled Payment for Care Improvement:
   i. Model 1: Retrospective Acute Care;
   ii. Model 2: Retrospective Acute Care Episode & Post Acute;
   iii. Model 3: Retrospective Post Acute Care; and
   iv. Model 4: Prospective Acute Care.

d. Capacity to Spread Innovation:
   i. Partnership for Patients;
   ii. Community-Based Care Transitions; and
   iii. Million Hearts.

e. Health Care Innovation Awards.


g. Initiatives Focused on the Medicaid Population:
   i. Medicaid Emergency Psychiatric Demonstration;
   ii. Medicaid Incentives for Prevention of Chronic diseases; and
   iii. Strong Start Initiative.

h. Medicare-Medicaid Enrollees:
   i. Financial Alignment Initiative; and
   ii. Initiative to Reduce Avoidable Hospitalizations of Nursing Facility Residents.

H. **Ethics in Patient Referrals Act of 1989 (a/k/a the “Stark Law”).**

a. This law was enacted by Congress to limit the effect of financial relationships on physician referrals. The Stark Law is extremely technical with all quoted terms subject to regulatory or statutory definitions.

b. In general, it prohibits a “physician” from making a “referral” of Medicare patients to an “entity” for any “designated health services” when the physician has a “financial relationship” with said entity, unless an “exception” applies to the financial relationship.
I. Clash of Laws: Stark Law, Anti-Kickback Statute & VBPs.

a. The Stark Law and Anti-kickback Statute (“AKS”) were created to protect a volume-based payment system from overutilization and patient steering.

b. The strict liability (and extremely technical) nature of the Stark Law, the criminal penalties associated with the AKS and the scope of False Claims Act exposure (for violations of the Stark Law and AKS) makes compliance extremely important.

c. The financial exposure under all of these laws is enormous and has grown in scope in recent years. For example, the scope of penalties available under the False Claims Act has increased as follows:

i. Prior to 2016 adjustment, per-claim penalties were $5,500—$11,000;

ii. After Feb. 3, 2017, per-claim penalties are now $10,957—$21,916;

iii. And this is in addition to triple damages for underlying reimbursement.

J. The Stark Law: Is it Too Antiquated?

a. From Modern Healthcare:

i. Former Rep. Pete Stark has heard the critics’ calls to repeal the Stark law over the years, and he says he has come to agree with them. “I would like to just go back to the old law,” he said. “Those complications were added by high-priced lawyers who tried to build loopholes for their clients. The original law was pretty simple,” Stark said. “Basically it says anyone who takes a bribe or a split or a commission or a kickback in exchange for referring services gets five years or a $50,000 fine.” (Pete Stark, Aug. 2, 2013).
K. Overview of Stark Law’s Application:

L. Review of Stark Law Legislative and Regulatory History.

a. Stark I statute; passed in 1989; fairly limited in scope.

b. Stark II statute; passed January 1, 1995; broad array of designated health services included.

c. Stark I final regulations; effective September 13, 1995.

d. Stark II proposed regulations, issued in 1998 (led to 13,000 comments).

e. Phase I Stark II regulations (led to only 140 comments).

f. Phase II Stark II regulations; effective 2004.

g. Phase III Stark regulations; effective 2007.

h. Inpatient Prospective Payment System (“IPPS”) Final Rule for 2009, issued in 2008 (major changes, including new definition of “entity”).

i. Waivers related to the Medicare Shared Savings Program.

j. Additional exceptions issued in 2016 Physician Fee Schedule.

a. What is a “financial relationship”?  
   i. Defined to include a direct or indirect ownership, investment or compensation relationship.

b. Overview of a direct financial relationship.  
   i. Remuneration passes directly between the referring physician (or family member) and DHS entity. For example:

   ![Diagram](https://via.placeholder.com/150)
   
   **Physician Employee** -> **Hospital**

   **Compensation, direct financial relationship**

   **DHS Referrals**

c. Overview of how an “indirect financial relationship” (see 42 C.F.R. 411.354(c)(2) for complete definition; the below is paraphrased) might arise:

   i. Unbroken chain of financial relationships between physician and DHS entity (here, hospital);
   ii. Physician receives aggregate compensation that takes into account volume or value of referrals or business otherwise generated for the DHS entity; and
   iii. DHS entity has knowledge of or acts in deliberate disregard or deliberate ignorance of such aggregate compensation.
N. Standard Physician-Hospital Relationship – Pre-Stark III.

Physician Compensation, direct exception required

Possible Indirect Comp. Arrangement
O. “Stand in Shoes” Rule– Stark III and IV.

Clinic is a “physician organization” (defined at 42 CFR 411.351).

Physician owner “stands in shoes” of group practice. A “group practice” is defined at 42 CFR 411.352. Key guidance on how the “stand in the shoes” rule applies is at 42 CFR 411.354(c)(2)(iv) and (c)(3).

Rules are different for physician organizations that do not have physician owners (e.g., nonprofit corporation). Indirect compensation analysis still available.

P. Stark Law Terminology.

a. Designated Health Services (defined at 42 CFR 411.351):
   i. List of specific services. These include:
      - Inpatient and outpatient hospital services;
      - Radiology and certain other imaging services;
      - DMEPOS;
      - Radiation therapy;
      - Clinical lab services;
      - Home health services;
      - Physical therapy, occupational therapy, speech language pathology; and
      - Outpatient prescription drugs.
   ii. It is important to understand how Stark Law applies to DHS and seemingly separate or independent financial relationships. If all of the elements of Stark Law are triggered and an exception cannot be met, then DHS referrals cannot be made (even if the financial relationship appears unrelated to the type of DHS at issue). For example, a physician and a hospital that have a services agreement under which they share financial risk in treating a group of patients under a commercial payor’s total cost of care contract may have a “financial relationship” (e.g., compensation arrangement) under the Stark Law. If the physician refers Medicare patients for DHS to the hospital, the agreement at issue will need to meet a Stark Law exception regardless of the fact that the commercial payor’s VBP has no specific connection to the Stark Law.
b. Definition of “entity” (42 CFR 411.351). An “entity” includes:
   i. Party that bills for the DHS;
   ii. Party that performs services that are billed as DHS. This change in the definition of “entity” is what resulted in many “under arrangements” arrangements no longer being permitted under the Stark Law.

Q. Other Key Laws Relevant to VBPs: Comparison of Stark Law and Anti-Kickback Statute.
   a. There is still some misunderstanding that Stark Law and Anti-kickback Statute (“AKS”) are the same.
   b. The AKS criminalizes the offering or receipt (and soliciting and paying) of remuneration in exchange for referrals or directing of federal health care program business.
   c. The AKS is a broader statute, less technical and less definition driven than the Stark Law.
   d. The Stark has no intent element, while the AKS does.
   e. Parties must separately analyze arrangements under AKS.
   f. AKS’ statutory “exceptions” and regulatory “safe harbors” are not required for compliance.
   g. However, the Stark Law requires meeting an exception, if the law is triggered.

R. Other Key Laws Relevant to VBPs: Beneficiary Inducement Civil Monetary Penalty (CMP).
   a. The Beneficiary Inducement CMP statute prohibits any person or entity from offering remuneration to a Medicare or Medicaid beneficiary if that remuneration is likely to influence the beneficiary's selection of a health care provider.
   b. The Office of Inspector General (“OIG” has issued numerous advisory opinions analyzing the beneficiary inducement CMP. Many of these opinions are helpful in understanding whether value-based goals of encouraging behavior by beneficiaries (through provision of various forms of rewards) will create regulatory issues.
   c. In 2016 HHS amended the definition of “remuneration” to include exceptions which went into effect on Jan. 6, 2017. The new exceptions apply to:
      i. Copayment reductions for certain hospital outpatient department services;
      ii. Certain remuneration that poses a low risk of harm and promotes access to care;
      iii. Coupons, rebates, or other retailer reward programs that meet specified requirements;
      iv. Certain remuneration to financially needy individuals; and
v. Copayment waivers for the first fill of generic drugs.

S. **Other Key Laws Relevant to VBPs: Gainsharing CMP.**

a. The “gainsharing” CMP viewed for many years as key obstacle to quality/value-based payment initiatives. This is because it arguably prohibited financial incentives to “reduce” (or make more efficient) care.

b. Congress amended the language related to gainsharing when it passed MACRA.

c. Originally, a hospital was prohibited from knowingly paying a physician to induce the physician to reduce or limit any services provided to Medicare or Medicaid beneficiaries.

d. MACRA changed the prohibition “any services” to “medically necessary services”. Now, hospitals cannot knowingly pay a physician to induce the physician to reduce or limit medically necessary services provided to Medicare or Medicaid beneficiaries.

e. OIG has issued numerous advisory opinions over the years that can be used as a roadmap for designing gainsharing arrangements.

T. **Stark Law Exceptions.**

a. Key Stark Law Exceptions:

i. There are numerous exceptions of varying scope and complexity available under the Stark Law.

ii. There is a significant difference in the scope of “general” exceptions (42 CFR 411.355) as compared to “ownership” exceptions (42 CFR 411.356) and “compensation” exceptions (42 CFR 411.357). Key general exceptions include:

iii. Physician services

iv. In office ancillary services. Broad in scope, but very technical. Key elements include:

   - Restrictions on who can bill for services;
   - Restrictions on where services can be provided;
   - Restrictions on who can perform (or supervise performance of) the service;
   - Requires satisfaction of “group practice” definition. Numerous requirements to be a “group practice, including:
     - Substantially all test;
     - Range of care test;
     - Number of physicians;
     - Single legal entity; and
     - Productivity bonus and profit sharing “special rules”

v. Academic medical centers—not appropriate outside of academic medicine, but broad in scope for qualifying parties.
b. Bona Fide Employment relationships (compensation). Key elements include:
   i. The entity has a bona fide employment relationship with physician;
   ii. Employment for identifiable services;
   iii. Remuneration under employment agreement is consistent with fair market value and does not take into account, directly or indirectly, volume or value of any referrals; and
   iv. The agreement is commercially reasonable even if no referrals were made.

c. Personal service arrangements (compensation). Key elements include:
   i. Agreement is in writing and specifies the services covered by the arrangement;
   ii. The aggregate services do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
   iii. Compensation is (1) set in advance, (2) does not exceed fair market value, and except for physician incentive plans, (3) is not determined in a manner that takes into account the volume or value or any referrals or other business generated.

d. Fair market value arrangements (compensation). Key elements include:
   i. Arrangement is in writing and covers only identifiable items or services, specifies the timeframe, and specifies set-in-advance compensation that will be provided which must be consistent with fair market value and not determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician;
   ii. The arrangement is commercially reasonable and furthers the legitimate business purposes of the parties; and
   iii. The arrangement does not violate any Federal or State laws

e. Prepaid plans exception (general):
   i. Services furnished by organization (or contractors and subcontractors) to enrollees of certain prepaid health plans.
   ii. Specific list of plans in the regulation that are protected. Plans include:
      ➢ An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M;
      ➢ A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U;
      ➢ An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1);
A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act);

A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422;

A MCO contracting with a State under section 1903(m) of the Act;

A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438;

A health insuring organization (HIO) contracting with a State under part 438, subpart D;

An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

Risk-Sharing Arrangements (compensation):

i. Compensation under a risk sharing arrangement (e.g., withholds, bonuses, risk pools) between MCO or IPA and a physician (directly or indirectly, via subcontractor) for services provided to enrollees in a health plan.

ii. The arrangement does not violate the AKS or any other Federal or State law.

Application of “indirect compensation arrangement” definition and exception for “indirect compensation arrangements”:

i. Key is to understand whether the regulatory definition of indirect compensation arrangement has been satisfied by the facts at issue in a particular relationship.

ii. The indirect compensation received by the referring physician must be fair market value for services provided and not determined in any manner that takes into account the volume or value of the referrals or other business generated by the referring physician for the entity furnishing the DHS.

iii. The arrangement must be in writing, signed by all parties, and specify the services covered by the arrangement.

iv. Arrangement cannot violate AKS or other federal/state laws.

U. Other Stark Law Exceptions

a. Each “financial relationship” must meet an exception (if the Stark Law is triggered). Thus, other exceptions may be important even where quality-based payment not clearly relevant (e.g., time share arrangement, lease for imaging equipment, recruitment arrangement, retention subsidy, etc.).

b. Other relevant exceptions include:

i. Rural provider;
Physician recruitment;
iii. Isolated transactions;
iv. Non-physician practitioner compensation;
v. Remuneration “unrelated” to DHS;
vi. Payments by a physician;
vii. Space rental;
viii. Equipment rental;
ix. Timeshare arrangements.

II. Fraud and Abuse Waivers

A. Sec. 1115A(d)(1) of Social Security Act authorizes HHS to waive fraud and abuse laws as necessary for Center for Medicare and Medicaid Innovation (“CMMI”) programs.

a. Medicare Shared Savings Programs Waivers created separately under Sec, 1899(f) of SSA.
b. No general waivers or exceptions have been issued to allow physicians and hospitals to participate in VBPs without triggering exposure under Stark Law and/or AKS.
c. Existing waivers provide helpful protection for providers participating in specific VBPs but they are complex and do not apply beyond the specific program under which they were created.
d. The waivers only apply to specific entities within the programs that meet all of the enumerated conditions.
e. Waivers are temporary.
f. Existing exceptions and safe harbors (and other options) remain.

B. The Department of Health and Human Services has issued fraud and abuse waivers and related guidance documents in connection with the following programs:

a. Pioneer Accountable Care Organization (ACO) Model.
b. Bundled Payment for Care Improvement (BPCI) Models.
c. Health Care Innovation Awards (HCIA) Round Two.
d. Comprehensive ESRD Care (CEC) Model.
e. Comprehensive Care for Joint Replacement (CJR) Model.
f. Maryland All-Payer Model Care Redesign Program.
g. Medicare Diabetes Prevention Program (MDPP) Expanded Model.
h. Medicare Shared Savings Program.

C. Waivers for Innovation Center Models

D. The general approach to waivers includes the following characteristics:

a. They are not mandatory. Parties can use exceptions, safe harbors, etc., as available under the relevant facts.
b. The failure to qualify for a waiver does not equal a violation of the Stark Law or AKS (providers can comply in other ways).
c. Waivers tend to protect financial contributions necessary to get a VBP arrangement off of the ground.
d. Incentive payments (to reward certain outcomes or behaviors) are also protected.
e. Gainsharing/distribution payments are also protected.
f. In-kind payments/beneficiary incentives are often protected too, as this reflects the importance of getting patient buy-in to an outcomes based model.

E. Waivers tend to share the following common challenges:

a. There is often a very limited scope in terms of what is protected.
b. There is always quite rigorous guidelines around provider eligibility and qualifications, as well as a number of very precise standards that must be met.
c. The temporary nature of waivers suggests that they will not offer permanent protection.
d. Waivers tend to complex in application and the practicality of adopting and following them must be measured on a case-by-case basis.
e. Waivers are limited to CMS run programs.
f. The narrow drawing of waivers may limit parties’ ability to innovate.

F. MSSP (Medicare Shared Savings Program) Waivers.

a. The MSSP was created by the ACA to permit care coordination under Medicare.
b. The Stark Law, AKS, gainsharing CMP, beneficiary inducement CMP (and antitrust and tax exemption) standards all were cited as potential hindrances to intended collaboration among providers via ACOs (and related CMMI projects).
c. Various iterations of ACO waivers since ACA passed. CMS and OIG jointly issued SSP Final Waivers in October 2015
d. Waivers relevant to Stark Law include:
   i. ACO Pre-Participation Waiver;
   ii. ACO Participation Waiver; and
   iii. Shared Savings Distribution Waiver.
e. Other waivers as well:
   i. Compliance with Stark Law (waives AKS); and
   ii. Patient incentives (waives AKS and CMP).
III. **2018 Stark Law Updates**

A. **Bipartisan Budget Act** signed into law on February 9, 2018.

B. **Codified into Stark Law** statute certain of 2016’s regulatory changes

C. **Eases “in writing” Requirement** by any means established by the Secretary including “contemporaneous documents evidencing the course of conduct” between the parties involved.

D. **However Congress Increased Penalties** for intentional violations under AKS from $25,000 to $100,000 per violation and doubled potential prison time from five to ten years

IV. **Disconnect Between Existing Exceptions and Goals of Value Based Programs.**

A. **The Stark Law directly impedes VBP’s** that Congress and commercial health insurers have promoted.

B. **There is Very Limited Ability to Get Guidance** from regulatory agencies with oversight (e.g., Stark Law advisory opinions).

C. Significant difficulty exists in distinguishing between “technical” and “substantive” violations of the Stark Law.

D. **The “Volume or value of referrals” Standard.**

   a. Providers have struggled to understand whether the Stark Law’s “takes into account the volume or value of referrals” (or “other business generated”) is a subjective or objective standard.

   b. The term is defined in Stark Law’s “special rules” on compensation (42 CFR 411.354(d)(2) and (3)).

      i. The term is then deployed in multiple exceptions:

         ➢ Most exceptions prohibit compensation that takes into account the volume or value of DHS or other business generated;

         ➢ The employment exception is narrower and only applies the restriction on DHS (not “other business generated”).

      ii. The compliance focus is on setting compensation in a manner that does not take the volume of referrals into account (and then keeping it that way throughout the arrangement):

         ➢ For example, the manner in which providers are able to articulate a non-referral based rationale for compensation terms, bonuses, incentive programs, quality rewards, etc., is critical.

         ➢ The key is to understand what kinds of adjustments can be made to compensation without creating a “volume/value” problem.
iii. Business leader commentary (e.g., remarks in emails, notes from meetings, presentations about business development, metrics tracking referrals and tying them to compensation, etc.) has created many volume/value problems in the past. This is particularly the case when the “business development” discussion is devoid of context.

iv. Providers who can point to protocols, metrics, etc., and corresponding compensation, that does not take into account volume, value of referrals and/or other business generated are in better position to defend their relationship.

v. Previous OIG guidance helps illustrate what is likely to be helpful support for payment terms. For example, in many gainsharing advisory opinions it is clear that OIG is focused on whether providers can point to objective methodologies in use for quality, credible verification of meeting those standards, legitimate benchmarks, etc.

vi. Compliance with the “takes into account” element is especially important for physician arrangements with hospitals and incentive-based arrangements funded with hospital revenue. This is because of the broad scope of inpatient and outpatient hospital services as a category of DHS.

E. Stark Law’s Guidelines on “Requiring” Referrals

a. This is a peculiar concept, considering that the point of the Stark Law is to regulate financial relationships that induce referrals. However, certain compensation arrangements requiring a physician to refer to a particular entity are permitted under 42 C.F.R. §411.354(d) (4) when the arrangement is:

i. “Set in advance” for the term of the agreement;

ii. Consistent with “fair market value” (does not vary with volume or value of referrals);

iii. Permits the referral requirement to be negated if the patient (or the patient’s insurer) expresses a different choice, or if the referral is not in the best interests of the patient in the judgment of the physician;

iv. Limited solely to the physician’s services covered in the scope of the agreement;

v. Reasonably necessary to effectuate the legitimate purpose of the compensation arrangement;

vi. Otherwise meets an applicable exception.

F. Stark Law’s Definition of “Fair Market Value”.

a. Fair market value (“FMV”) is defined at 42 CFR 411.351.
b. CMS has made clear that it does not take the position that there is only one way to determine whether compensation is fair market value.
c. For example, CMS has indicated that multiple, objective independent surveys can be used but so can internal determinations.
d. The burden on establishing FMV is with the parties.
e. A key challenge to navigate is the difficulty in squaring FMV standards (many of which are designed for RVU productivity) to reimbursement based on outcomes, quality, efficiency, etc.

G. Many Stark Law exceptions also require that an arrangement be “commercially reasonable”

a. CMS has not defined commercial reasonableness. The most detailed articulation comes from the 1998 Stark Law proposed rule. Additional commentary and examples have been issued in subsequent rulemakings.
b. The key focus in determining commercial reasonableness appears to be whether the arrangement would make business “sense” absent referral-based considerations. The question is whether the arrangement is objectively a sensible, prudent business arrangement:
   i. It needs to make commercial sense if entered into by reasonable entity of similar type, size and physician (of similar scope, specialty), even in the absence of referrals. For example, it might not be commercially reasonable for a hospital to pay more to rent a CT machine from a referring physician than it would cost if the hospital simply purchased the CT.
   ii. DHS entities need to monitor both the offer of quality based arrangement and payment under the commercial reasonableness standard.

c. Given attention given to commercial reasonableness in enforcement actions and qui tam cases, there has been an increasing focus on commercial reasonableness opinions (similar to fair market value opinions).
d. Growing attention on this issue, particularly for physician—hospital arrangements. For example, regulators have focused attention on whether hospital’s subsidy of a physician's practice is “commercially reasonable”.

H. Stark Law standards on compensation that is ”set in advance” and “in writing”.

a. The Stark Law’s special rules on compensation (42 CFR 411.354) define “set in advance”. The term is then deployed in numerous exceptions (e.g., fair market value arrangements, personal services arrangements, leases, etc.). However, the “set in advance” standard is not part of several key exceptions (e.g., group practice and in-office ancillary, employment, etc.).
b. Many other exceptions include a requirement that the arrangement be “in writing”:
   i. For example, the requirement is relevant to the fair market value, leasing, personal services and indirect compensation arrangement exceptions.
   ii. However, the writing requirement is not part of several key exceptions (e.g., group practice and in-office ancillary, employment, etc.).
   iii. It is important to be able to identify quality measures, performance metrics, methodology for analysis and measurement, etc., in a way that does not run afoul of “in writing”.

I. Commentary in Stark Law that Supports Use of Exceptions in Value Based Arrangements.

   a. In the Phase I rulemaking (2001), CMS indicated that it was permissible to base compensation on “quality measures unrelated to” volume or value of DHS referrals or other business generated by physician.
   b. In the Phase II rulemaking (2004), CMS reviewed a question from a commenter regarding whether the employment exception permitted paying physicians “based on appropriateness of referrals as measured by quality-oriented” records, guidelines, protocols, etc. CMS indicated that nothing bars payments based on quality measures, so long as compensation is FMV and not based directly or indirectly on volume/value of DHS referrals. CMS also noted that there was no prohibition on payments based on hitting appropriate benchmarks related to providing preventative care or meeting patient satisfaction goals.
   c. In the Phase III rulemaking (2007), CMS reiterated its Phase II commentary regarding permissibility of paying based on quality measures unrelated to referrals (as long as exception met) and described rewards sharing demonstrations programs under Medicare Modernization Act and Deficit Reduction Act.

V. Potential Solutions for Squaring Incentives of Value-Based Programs with Regulatory Restrictions in Stark Law and AKS

   A. A Regulatory or Legislative Fix?

   a. Many observers focus on whether the seeming shift in Medicare payment to VBPs will remove the rationale for the Stark Law.
      i. For example, if a qualifying “group practice” receives specified percentage of income through bundled programs, one idea would be to remove the Stark Law’s restriction on referrals.
b. Another idea is to create new definitions of key terms, such as the “volume or value” of referrals:
   - For example, creating a “safe harbor” for all compensation arrangements that were initially created at a FMV rate.
   - That does not vary or change during the term of the arrangement based on the “volume or value of referrals”.

c. New definition of “Fair Market Value”:
   i. For example, establish a statutory standard or a “safe harbor” for compensation from a DHS entity to a physician that is or below the 75th percentile in the national compensation statistics in the same specialty as shown in survey data (determined by HHS).

d. New definition of “Commercially Reasonable”.
   i. One idea is to remove the standard altogether due to its inherent ambiguity.
   ii. Another idea is to define it to mean services or items are of a similar kind or type of services or items used by similarly situated entities.
   iii. The point is to distinguish the term from whether the purchased services or items are profitable on a standalone basis.

B. U.S. Senate is Reviewing the Issue.

a. On June 30, 2016, the Senate Finance Committee published a white paper called, “Why Stark, Why Now?” with suggestions on how to fix Stark and AKS in the face of MACRA, including:
   i. Repeal AKS and Stark. This seems unlikely because these laws do catch many bad actors, fee-for-service medicine will continue for some time and the future of value-based payments is not clear under current administration.
   ii. Repeal compensation arrangement prohibitions. This would be in line with Pete Stark’s view of the law because his focus has mainly been about physician ownership.
   iii. Create new risk revenue waiver/exception. The idea would be for an automatic waiver to apply once value based revenue at a practice hits a certain target (so long as the participating entity meets other CMS program integrity standards or quality metrics).
   iv. Create new or expand current restricted waivers. This might include expanding existing waivers to cover value-based programs used by non-government payors. The ACO waivers are usually cited as the best example of sufficiently expansive waivers. A related idea is to make the existing CMMI waivers permanent.
   v. Create new exceptions. This could include expanding HHS’ authority to create exceptions tied to value-based programs.
   vi. Special compensation rule. In addition to the discussion above related to changing the definitions of fair market value, takes into account the volume or value of referrals or commercial
reasonableness, an idea is to automatically deem MACRA reimbursement to meet fair market value and volume/value standards.

vii. Modify existing exceptions. One option would be to expand the current general exception for prepaid plans (discussed above) so that it clearly applies to value based programs.

viii. Expand HHS’ authority in the area of waivers, exceptions, and advisory opinions. Ideas include creating a new APM exception or a new exception for APMs within integrated delivery systems. However, the last time CMS proposed a new Stark Law exception in this area (for gainsharing arrangements), it was deemed so complex that CMS ultimately withdrew the proposal.

b. Advisory Opinion Authority:
   i. Very small number of Stark Law advisory opinions have been issued.
   ii. It has been proposed that CMS’ advisory opinion authority should be changed to expressly allow CMS to advise on proposed or hypothetical compensation and ownership arrangements.
   iii. Another idea is preventing the agency from declining to issue an opinion, based on the grounds that a similar arrangement between other parties is subject to an investigation.

c. Easing the burden for CMS to Promulgate New Regulatory Exceptions:
   i. Current constraints prevents CMS from creating exceptions that pose minimal risks.
   ii. Easing this burden would allow for CMS to create exceptions more efficiently for situations with minimal risk.

d. Legislation has been introduced:
   i. Medicare Care Coordination Improvement Act of 2017 (HR 4206).
      ➢ Provides HHS with identical waiver authority as applies to ACOs under MSSP for entities participating in:
         o Advanced APMs;
         o APMs approved by Physician-Focused Payment Model Technical Advisory Committee;
         o MIPS APMs;
         o Other APMs specified by HHS;
         o Must have written arrangement, signed by parties, semi-annual reports to HHS.
   ii. Medicare Care Coordination Improvement Act of 2017 (HR 4206).
      ➢ Provides HHS broader authority to create exceptions:
         o Changes “risk of program abuse” to “significant risk”, including “those that would promote patient care coordination, quality improvement...”;
         o CMS prohibited from imposing new regulatory requirements that adversely impact physician care coordination in MIPS or physician participation in APMs.
➢ New statutory (general) exception that removes “volume or value” prohibition;
   o For all types of APMs;
   o Written arrangement, signed, services identified, semi-annual reports to HHS, tied to APM model and at FMV.

iii. Stark Administrative Simplification Act of 2017 (HR 3726)’’:
➢ Continued emphasis on addressing “technical” violations;
➢ Bipartisan bill, approved unanimously by House Ways & Means (Dec. 21, 2017);
➢ Creates alternate self-disclosure option and sets penalties at $5000 or $10,000 (depending on timeliness);
➢ Placed on Union Calendar (Calendar No. 354);
   o House just finished Bill 149.

C. 2018 Request for Information.

a. In 2018 CMS issued a request for information asking for public input on how to address any undue impact and burden of the Stark Law.

b. CMS specified requests for:
   i. Existing or potential arrangements that involve DHS entities and the levels of risk the parties involved bear;
   ii. Scope and timeframe of the arrangement;
   iii. What additional exceptions are necessary to protect these arrangements;
   iv. Utility of the current exception;
   v. Definitions of critical terminology.
Electronic Health Record: Contracting Data Security

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**Intro**

Below we address some of the key components of Electronic Health Record and other IT agreements.

**Fees, Pricing and Payment**

If we as attorneys are honest with ourselves, many of the artful clauses we draft in EHR contracts will be forgotten and collect dust once the contract is signed. Not so with fees and pricing clauses: In my experience these sections are among the most-frequently reviewed and discussed throughout the customer-vendor relationship. Also, if pricing and fees provisions are drafted so that payment to the vendor lines-up with success milestones for the customer, disputes become less likely and also other sections of the contract, such as detailed testing and acceptance measures, warranties, specifications, or performance metrics, can be shortened and simplified.

Many of the ideas in this section are common to services and other contracts in general and may be familiar to experienced contract negotiators.

The following are key elements to consider when drafting or negotiating fees, pricing and payment provisions of an EHR system contract:

- **Up-front, at initial contract formation, is your best time to negotiate fees, pricing and payment.** Once the customer has signed the contract and invested effort in implementing an EHR system, there is substantial cost and effort to investigating alternatives and making a switch. Customers should use the initial contract negotiation to negotiate not only favorable initial pricing, but also to lock in future-pricing. This is a competitive landscape, and in my experience pricing is highly negotiable; this is especially true at the end of the fiscal quarter and year for the particular vendor.

- **Be wary of pure time-and-materials for services pricing,** as this method shifts substantial risk to the customer. Remember, for an 80% complete IT project, where you have paid 80% of the fees, but which falls apart and is never completed, is probably worth close to zero, as any replacement vendor will need to start from close to scratch in most cases.

Milestone-based payments for services and implementation are preferable, with a substantial portion reserved for a final payment upon a successful launch in a go-live environment. If fees are on a time-and-materials basis, propose a ___% (perhaps 20%) hold-back from each invoice which is not released until successful launch in a go-live environment. This hold-back is a powerful motivator to get vendors to finish their work and complete “punch-list” items.
Thoughtfully and precisely define any metrics used to drive fees, such as pricing by “user,” “facility,” “claim,” or “transaction.” Give examples. Disputes over “counting” as it relates to fees are among the most frequent disputes in EHR contracts. For example, I have seen “user” defined at least a half-dozen different ways in different contexts. Also, consider having the vendor scope your environment and provide in writing a proposed calculation of your initial use volume and related fees; Some customers experience an unwelcome surprise when the vendor first tabulates the customer’s use volumes in a live environment and discovers the resulting fee is substantially higher than expected.

Negotiate rates in advance in case you want to increase your volume of use (for example, increase your user-count). If possible try to negotiate a fee-reduction if your use volume decreases. This issue can be especially expensive if your organization divests of a location or business unit: It is very expensive to continue to pay for substantial volume/users you no longer need.

For services, lock in rates (if hourly/daily) for the initial term, and cap any increase (perhaps at CPI) for successive or renewal terms.

For implementation of complex IT systems fixed-fee for services is uncommon but not unheard-of. If you require fixed-fee, be prepared to see a premium / markup charged by the vendor, and then be very explicit and extensive in your description of the in-scope and out-of-scope elements. Some experienced vendors have personnel specifically devoted to spotting and documenting alleged “out of scope” items, and then initiating the change order (and fee increase) process.

You may want additional “modules” in the future; lock-in pricing or a discount percentage for additional modules.

Think carefully about when various fees should commence. For example, consider proposing that license fees and maintenance / support fees do not commence until after installation / implementation is complete. Vendors will often draft agreements so that fees begin to accrue at contract signing, and otherwise front-loading payments and fees. Customers, delaying payment until after successful delivery and testing of items is to your advantage.

Personnel

The quality and consistency of the vendor-personnel assigned to your project will have a significant impact on the success of your project. If you have been introduced to specific vendor personnel during the sales process that you like, be sure to lock them in in a contract provision so they are actually assigned to your project and don’t disappear once you sign the agreement.
Also, negotiate a provision to minimize key personnel turnover. Top IT talent is in high-demand, and turnover in the health-IT and tech industries is substantial. Of those cases / contracts where a substantial IT project has foundered or failed, I almost-always find high turnover among key vendor (and customer) personnel.

Sample clause:

**Personnel**

a. **Right to Approve Personnel.** Client’s COO or other Client personnel as designated by Client, shall preapprove all Service Provider employees or contractors assigned to perform Services to Client hereunder (“Service Provider Personnel”). Service Provider shall provide Client with copies of resumes or other information reasonably requested by Client regarding potential personnel. All Service Provider Personnel shall have sufficient skill and training to perform the tasks assigned to them under this Agreement and shall hold any and all required licenses and/or certifications.

b. **Right to Reject Service Provider Personnel.** Client reserves the right to reject any of Service Provider Personnel at any time, at Client’s sole discretion. If any individual is rejected, Service Provider shall replace that individual without any degradation in Services to Client.

c. **Continuity of Service Provider Personnel.** Service Provider agrees that Service Provider Personnel shall not be removed from a specific project with Client until completion, so long as such person remains employed or engaged by Service Provider, unless Client requests removal of such person.

d. **Non-Billable Time.**

   i. **During First 30 Days.** If a Service Provider Personnel resigns, is terminated for cause or is removed by Service Provider at Client’s request during the first thirty (30) calendar days of such Service Provider Personnel providing Services, Service Provider shall waive the fees with respect to the last fifteen (15) days the Service Provider Personnel actually worked, unless the individual has worked fewer than fifteen (15) days, in which case Service Provider shall waive the fees for all days worked by such individual.

   ii. **After First 30 Days.** If a Service Provider Personnel resigns, is terminated for cause or is removed by Service Provider after the first thirty (30) calendar days of such Service Provider Personnel providing Services, Service Provider
shall waive the fees with respect to the last thirty (30) days the Service Provider Personnel actually worked.

No Plan to Sunset or Discontinue Software / Service

Once you have implemented your new EHR system, you want to ensure you can enjoy the system for a number of years. Unfortunately, due to vendors’ desire to push clients to new cloud-based systems, marketplace consolidation and M&A activity, and other causes, vendors sometimes discontinue support for EHR systems (for installed software) or force customers to migrate to a successor product when the prior product is discontinued. These vendor-forced or vendor-encouraged changes can be time consuming, expensive and disruptive.

Consider adding the contract term below to reduce your risk. Note, even if you are not successful is getting the clause below into the contract, mere inclusion of the redline or comment may trigger a discussion of the issue with your vendor prior to contract signing; you may discover facts, such as a vendor-plan to discontinue support for your system, that persuade you to change vendors or systems.

Sample clause:

No Plan to Sunset. Vendor represents and warrants that it has no present intention to sunset or discontinue offering the Software Product or support for the Software Product, and shall not do so within five (5) years of the date of this Agreement. In the event Vendor discontinues or substantially diminishes offering or providing support for the Software Product, then in addition to any other remedies to which Customer may be entitled, Customer shall receive a license at no fee to any successor or replacement product on terms at least as favorable to Customer as those set forth in the 2018 License Agreement. Customer shall not be liable for any incremental or additional license fees related to the successor or replacement product even if the successor or replacement product has additional or different features or modules beyond those licensed in the Software Product.

Representations and Warranties

Disconnect between what a vendor sales-team describes during the sales process, and what is actually delivered, is a frequent EHR customer complaint. Clear and robust representations and warranties can protect against this risk as well as protecting against a host of other risks. If you engage in an RFP process (which we encourage), consider including a provision in the RFP document that you intend to incorporate by reference the vendor’s responses as part of the definitive agreement.

Elements of sample warranty clause (this sample is not intended to be all-inclusive or include standard warranties such as ‘authority’ or ‘no conflict,’ etc.):
Representations and Warranties. Vendor represents and warrants as follows:

a. Conformance with Documentation. The EHR Subscription Software shall operate in material conformance with all Documentation for the full subscription term under this Agreement. “Documentation” means all Vendor-provided documentation relating to the features, functions, and use of the EHR Subscription Software, including, without limitation, any Service Level Description and any other any RFP response, proposal, sales material, and similar documentation or information provided by Vendor to Customer, including, without limitation, the Proposal dated ____________.

b. Interoperability. Vendor will provide Services including, without limitation, installation and support, so that the EHR Subscription Software will interoperate with Customer’s other software and systems with which it is intended to interoperate i.e., ______________ [billing system/ software], [other key systems].

c. Backup: Disaster Recovery. Vendor shall maintain and implement backup procedures and disaster recovery and avoidance procedures within industry standards designed to ensure that access to and use of the EHR Subscription Software is not interrupted during any disaster and to safeguard the accuracy and integrity of the Customer Data. Vendor shall provide Customer with a copy of its current backup plan and disaster recovery plan and all updates thereto upon Licensee’s request and shall comply with such plans in all respects. All requirements of this Agreement, including those relating to security and service levels, shall apply to Vendor’s disaster recovery site.

d. Services. The Services shall: (i) be provided in a professional and workman-like manner; (ii) be performed by properly-trained and competent personnel who hold current licenses or certifications if required to be so licensed or certified by applicable law or industry standard; (iii) meet or exceed all industry standards applicable to the Services; and (iv) be in compliance in all respects with all specifications, performance standards, and descriptions furnished, specified or adopted by Customer.

e. No Virus. No software or other item provided by Vendor shall contain any virus, worm, time bomb, drop-dead device, remote off-switch or similar malicious code.

f. Exclusion from Federal Healthcare Programs. Vendor represents and warrants that it has not been excluded, nor any of its employees been excluded from payment for Federal healthcare programs, nor do they appear on the List of Excluded Individuals/Entities of the Office of the Inspector General of the Department of Health and Human Services.
Limit of Liability and Carve-Outs: What’s Market

Below is my subjective view of key issues and what is “market” or reasonable to propose in a Limit of Liability section in 2018.

- Liability is generally limited to fees paid, and damages are limited to exclude lost profits, incidental, consequential, and similar damages other than “direct” damages. It is reasonable for customers, however, to propose to make such a clause mutual. Depending upon your negotiation power, it may be possible to increase general liability to 2x of fees paid rather than 1x, although 1x is the norm.

- Although it is “market” to agree to a limit of liability clause, it is also “market” to have certain carve-outs to the limit of liability clause, where liability is not capped. These areas include: breach of confidentiality and security provisions, indemnity (particularly for breach of IP and for security breaches), violation of laws, and physical injury and property damage. In some cases, if the vendor refuses to create a carve-out to the cap, a “super-cap” of perhaps 10x of fees paid is applicable to these categories of damages.

- For a security breach, consider also stipulating that direct damages include: legal fees, computer forensic/consultant fees, cost of notice to impacted individuals, and credit monitoring for impacted individuals for 12 or 24 months.

Interoperability

The interoperability of EHR systems is a key factor for obtaining certain government incentives related to use of an EHR, as well as for compliance with the Stark exception and anti-kickback safe harbor for hospitals that may offer a discount to a physician or physician group for implementation of an EHR. All health care providers should ensure that vendors will not limit interoperability, and that any entity offering financial incentives for implementing an EHR also does not limit the system’s interoperability with any other EHR or any other provider system.

The following is a sample clause for a shared EHR system offered by hospital to physician group. The language could be used whether or not the recipient of an EHR is offered a discount.

Section X. Interoperability. Medical records that are part of the EHR System through patient treatment at Hospital will be available to Physician Group’s Authorized Users at the request of a patient. Medical records related to patient treatment of Physician Group patients will become part of Hospital’s EHR System and will be available to appropriate providers within Hospital, and to other physician groups participating in the EHR System. Physician Group acknowledges that any use or access to the EHR System by Physician Group creates and/or adds to a general or “composite” medical record for each patient registered in the EHR System. As such, once a patient record is created, it becomes accessible by all registered users of the EHR System. (Each
Once a record for a patient is created within the EHR System, such record becomes part of the EHR System record, and cannot later be removed or withdrawn from the EHR System by Physician Group. The parties will determine other guidelines and level of intraoperability for the appropriate use of and access to records that are stored on the EHR System, as necessary. Neither party shall take any actions that would limit the intraoperability of the EHR System. Hospital shall enter into agreements with other affiliates that are substantially similar to this Agreement, and Hospital shall use its best efforts to enforce the confidentiality requirements applicable to all authorized users of the EHR System.

Certified EHR Technology

The use of certified EHR technology is important in that use of CEHRT providers health care providers with some degree of confidence that the EHR system or module offers the appropriate features and capabilities to ensure compliance with government incentive programs. It also gives some assurance that the products and systems are relatively more secure, and that they will work in concert with other EHR systems to the extent reasonably possible.

*The following sample language is from the healthit.gov guidance on EHR contracting (https://www.healthit.gov/sites/default/files/EHR_Contracts_Untangled.pdf), and is for use in agreements between health care providers and their EHR or EHR module vendors:*

Section X. Certified EHR Technology. As part of its standard support and without any additional license, implementation, support, or other fees or expenses, EHR Vendor will provide the following to Hospital so long as Hospital is receiving software maintenance under this Agreement:

(a) All versions of the Software necessary to satisfy all requirements in order to be Certified EHR Technology for use by Hospital and, at Hospital’s election, its non-employed medical staff, so that they can each qualify to receive all of the Medicare incentives available under HITECH beginning on [date] and will not be subject to any reduction in reimbursement as a result of a failure to use Certified EHR Technology as a “meaningful user.” Such software shall be provided: (i) with respect to the current definition of Certified EHR Technology, at least _____ months prior to [insert date used above]; and (ii) if the definition of Certified EHR Technology is revised thereafter or a different definition is used under successor laws or regulations, an updated version of the Software that satisfies each such revised definition at least _____ months before the revised definition becomes effective. Such new versions may be referred to as “Certified EHR Versions.”

As used herein, the terms “Certified EHR Technology,” “Health IT Module,” and “meaningful user” each have the respective meanings assigned to such terms in HITECH (and any subsequent amendments thereto) and in the regulations promulgated from time to time pursuant to HITECH, including whatever are then the most recent versions of HITECH and such regulations or any successor laws and regulations (the “Current Requirements”).

patient has only one record, accessible and charted to by all authorized health care providers.)
(b) All implementation, training, data conversion, and other services that may be necessary or appropriate
to reasonably assist Hospital in implementing each of the Certified EHR Versions that Hospital may, in
its discretion, elect to implement, and in becoming a “meaningful user.”

2. EHR Vendor hereby represents and warrants that as of the date of this Agreement, Version ___ of the
Software being licensed hereunder has been certified as a Health IT Module pursuant to the Current
Requirements;

3. EHR Vendor hereby agrees that it shall take all action necessary to assure that the representations and
warranties set forth in Section 2 above shall remain true and correct with respect to Version ___ and all
future versions of the Software at all times during the period in which Hospital is entitled to receive
software maintenance under the Agreement.

Data Security

Our clients should do as much vendor research as reasonably possible when selecting an EHR or other IT
vendor, including by contacting other users and asking to review data security policies and practices. It’s
also important to ensure appropriate data security language to the contract itself, and not rely solely on the
more generic security and privacy assurances found in most business associate agreements. If nothing
else, sometimes requesting additional language on data security can give clients a foothold to discuss
these issues both internally and externally to ensure that everyone is on the same page about the levels of
security expected. It is not unusual for a client’s IT team to have a different idea of what is needed from,
say, the salesforce of an IT vendor.

If a client is unable to get more specific data security requirements into the main contract, consider adding
any vendor responses to the data security review as a material part of the vendor’s “documentation.”

The following sample language contains very strong security requirements; it is unlikely that all vendors
would agree, but similar language would be useful with vendors storing or having access to large
amounts of client information:

Section X. Data Security. Client agrees to access the Solution and to store and retrieve data using third
party programs, including specifically Internet “browser” programs that support data security protocols
compatible with those specified by Vendor. Unless otherwise agreed in writing, the parties agree that all
software used to access the Solution will support the Secure Socket Layer (SSL) protocol. Vendor agrees
to maintain the security of Client Data using industry-standard (within the highly regulated health
industry) data security protocols, and other method reasonably deemed to be adequate for secure business
data and to notify Client immediately in the event of a breach or suspected breach of security involving
Client Data or Client Confidential Information. Vendor agrees to retain Client Data on a secure server
and to maintain data recover and data backup facilities in accordance with accepted industry practices.
Attached as Appendix ___ is a copy of Vendor’s security policy and disaster recovery policy, and Vendor
shall comply with such policies at all times. Vendor shall receive a successful SSAE Audit each year and
shall provoce a copy of such audit results to Client. Vendor shall defend, indemnify, and hold harmless
Client for all losses, damages, and costs associated with any loss, improper use, improper access, or
unauthorized disclosure of Client Data or Client Confidential Information in Vendor’s possession or
control, including but not limited to legal costs and costs associated with notifying affected individuals.
Transition Issues

Clients should ensure they are able to handle the “what next” part of EHR contracting when a vendor agreement comes to an end. The contract should include clear language that when the agreement or license terminates, the vendor will not withhold the client’s information, and that the vendor will help transition to a new service when appropriate. Costs for this transition can be negotiated, but clients should never be in a position of having their business hamstrung (and potentially failing in their obligations to patients) because they cannot access all of their data and/or patient records.

Sample Clause:

Section X. Transition of Client Data. In the event this Agreement is terminated or expires, Vendor shall reasonably cooperate with Client to transition services without damage to Client’s business or operations and will immediately make available to Client a file of the Client Data in such form or format as requested by Client. Under no circumstances shall Vendor refuse to provide Client with access to Client’s information and data. Further, upon prior written request from Client in the event of termination or expiration of this Agreement, Vendor will cooperate with Client, at Client’s cost and expense, to transition Client Data to another EMR service provider. Vendor will invoice Client and Client will pay Vendor according to Vendor’s standard rates for such transition services.
21st Century Healthcare – Telemedicine: Navigating the Legal Challenges of Licensing, Scope of Practice and Standard of Care

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What is Telemedicine

Telemedicine is the use of electronic communication technologies to provide clinical services to patients without an in-person visit, with the goal of improving the patient’s health status. The electronic communications or monitoring may be used for follow-up visits, management of chronic conditions, medication management, consultation with specialists, or other clinical services that can be provided remotely via secure video and audio connections.
Types of Telemedicine

• Store-and-Forward (Asynchronous)

• Remote Patient Monitoring

• Real Time Services

Store-and-Forward (Asynchronous)

• The electronic transmission of patient data among providers at different locations
• A secure way to share information
• Asynchronous – providers do not need to be reviewing the patient records at the same time
• Best suited for consulting with specialists, external resources
• Examples:
  – Teleradiology – a smaller facility can send x-rays to a remote radiologist for review and diagnosis
  – Teledermatology – a primary care physician can take a picture of a skin condition and send to a specialist for consultation
  – E-Consults, second opinions
• Benefits:
  – Patients can obtain specialty care, even if not available in their particular geography
  – Faster, more cost-effective than seeing a specialist
Remote Patient Monitoring

- The collection of health data from a patient in one location, and the transmission of the health data to a provider in a different location
- Can be done with active and live monitoring of information to flag for issues
- Alternatively, providers can receive reports of collated data for better ongoing care
- Often used for chronic care management
- **Examples:**
  - Monitoring vitals, blood pressure, glucose levels, heart rate, pulse, sleep patterns, weight
  - Information often gathered from wearable and mobile devices
  - Tele-hospitalist, tele-cardiology
- **Benefits:**
  - Can help identify issues quickly before they develop into bigger problems
  - Can help providers better understand patient behavior
- **Risks:**
  - Wearable devices – new, unproven applications

Real Time Services

- Live, two-way video encounter between a patient and a provider, or between providers
- “Skype” medicine – but with secure, private connections and HIPAA compliant technology
- Most often used for primary care, urgent care or follow-up issues
- **Examples:**
  - Patients with suspected pink eye, ear infection, influenza, rash, respiratory infections, lice
  - Tele-Neuro (strokes, sepsis, cardiology)
- **Benefits:**
  - Convenient, fast, cost-effective for patients
  - Opportunity to get immediate treatment
  - Not limited to physicians in your immediate area
- **Risks:**
  - Managing patients from distant locations
Telemedicine Statistics

- Kaiser Permanente (KP) is a national leader in telemedicine
- In 2015, of KP’s 110 million interactions between physicians and members, 56% were virtual, surpassing physical visits for the first time


CentraCare Health Telemedicine Stats

- **Fiscal Year 2017**: 8,300 visits via Telemedicine
- **Fiscal Year 2018**: 13,700 visits via Telemedicine
Practitioner Licensure

• 48 state medical boards (plus the District of Columbia) require that any physician providing care to patients via telemedicine is licensed in the state where the patient is located.
  – Kansas and New Mexico do not require licensure

• 15 states have special purpose telemedicine licenses
  – Minn. Stat. 147.032 Interstate Practice of Telemedicine

• Exceptions for infrequent or occasional consultations – 28 states
  – 5 states define occasional or infrequent
  – Delaware: fewer than six consults per year
  – New Mexico: no more than 10 patients per year
  – Wyoming: not more than seven days in any 52-week period.

Minnesota Licensure - Physicians

• Definition of telemedicine - Minn. Stat. 147.033
  “For the purposes of this section, ‘telemedicine’ means the delivery of health care services or consultations while the patient is at an originating site and the licensed health care provider is at a distant site. A communication between licensed health care providers that consists solely of a telephone conversation, e-mail, or facsimile transmission does not constitute telemedicine consultations or services. A communication between a licensed health care provider and a patient that consists solely of an e-mail or facsimile transmission does not constitute telemedicine consultations or services. Telemedicine may be provided by means of real-time two-way interactive audio, and visual communications, including the application of secure video conferencing or store-and-forward technology to provide or support health care delivery, that facilitate the assessment, diagnosis, consultation, treatment, education, and care management of a patient’s health care.”
Minnesota Licensure - Physicians

- Minn. Stat. 147.032 Interstate Practice of Telemedicine
  - Must be licensed without restriction in the state from which the physician provides telemedicine services;
  - No revocation or restriction of license in any jurisdiction;
  - Must not open an office in MN, meet with patients in MN, or receive calls in MN from patients; and
  - Must register with the Board annually.
- Exemption from telemedicine registration if services are provided
  - In response to an emergency medical condition (absence of immediate attention could reasonably put patient’s health in serious jeopardy . . . );
  - On an irregular or infrequent basis (less than once per month or fewer than 10 patients annually); or
  - In consultation with a physician licensed in MN and MN physician retains ultimate authority over diagnosis and care of patient.

Other Minnesota Licensed Professionals

- Nurses:
  - “The Minnesota Board of Nursing considers nursing practice as occurring in the state in which the client is located at the time nursing care is provided. If a nurse from another state is providing nursing care by telephone or other electronic means to a client located in Minnesota, the nurse must be licensed to practice nursing in Minnesota.”
- Physician assistants – no statute or statement from the Board
  - Medical Assistance pays for telemedicine services provided by “licensed health care providers.”
Scope of practice

- Providers must limit telemedicine practice to what is within the provider's scope of practice.
- Providers must also pay attention to what each state permits a provider to do:
  - I.e., some states require in-person encounters before providing telemedicine.
  - Definitions of “practicing medicine” or “telemedicine” may differ.
- Scope of practice is particularly important for non-physicians:
  - Most states permit non-physicians to practice telemedicine.
  - But the scope of practice for non-physicians in each state is different.
  - If there are supervision requirements for non-physicians, who provides the supervision for the provider?

Physician-patient relationship

- Minn. Stat. 147.033, subd. 2 Physician-patient relationship
  - “A physician-patient relationship may be established through telemedicine.”
- Fact scenario
  - Nurse practitioner sees patient in clinic; nurse practitioner thinks patient should be admitted to hospital; nurse practitioner calls hospitalist on duty and discusses potential hospitalization of patient; patient not admitted.
  - Does the patient have a physician-patient relationship with the hospitalist?
Duty of care

- Rather, “duty arises where it is reasonably foreseeable' that the injury would follow if the advice is negligently given.”
  - Based on two previous MN cases – one MN Supreme Court and one MN Court of Appeals case
- “Therefore, for 100 years in Minnesota, a physician has had a legal duty of care based on the foreseeability of harm. Although ours is the minority rule, it is by no means unique. This rule has served Minnesota sufficiently well, and we have no compelling reason to overrule our precedent.”
- *Warren v. Dinter* rejected the “curbside consult” characterization as a defense to liability

Standard of care

- Minn. Stat. 147.033, subd. 3 Physician-patient relationship
  - “A physician providing health care services by telemedicine in this state shall be held to the same standards of practice and conduct as provided in this chapter for in-person health care services.”
Telemedicine and prescribing

- Prescribing statutes written before widespread use of telemedicine
- State statutes are vague
- Many states require a physical exam or pre-existing physician-patient relationship prior to prescribing

Minn. Stat. 157.37 (d) A prescription drug order for [controlled substances and certain other drugs] is not valid, unless it can be established that the prescription drug order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:

- (e) For the purposes of paragraph (d), the requirement for an examination shall be met if an in-person examination has been completed in any of the following circumstances:
  - (1) the prescribing practitioner examines the patient at the time the prescription or drug order is issued;
  - (2) the prescribing practitioner has performed a prior examination of the patient;
  - (3) another prescribing practitioner practicing within the same group or clinic as the prescribing practitioner has examined the patient;
  - (4) a consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient; or
  - (5) the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.
Telemedicine and prescribing

- Federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 – designed to combat rogue internet pharmacies selling controlled substances online
  - Prohibited form-only online prescribing for controlled substances
  - Permitted prescribing of controlled substances via telemedicine if practitioner has conducted an in-person exam or meets a “practice of telemedicine” exception
  - Practice of telemedicine exceptions are outdated. Counter to direct-to-patient service models (e.g., substance use disorder treatment)
  - No “special registration” rules from the DEA
- 2018 SUPPORT Act included the “Special Registration for Telemedicine Act of 2018” requiring DEA to promulgate special registration regulations by October 24, 2019

Fraud and abuse

- Historically favorable treatment of telemedicine arrangements in OIG advisory opinions
  - AO No. 98-18 Ophthalmologist and optometrist equipment lease
  - AO No. 99-14 Health system and rural facilities partnership following expired telemedicine grants
  - AO No. 04-07 Health system and school-based clinics
  - AO No. 11-12 Telestroke program
- 2018 Advisory Opinion (No. 18-03)
  - FQHC provided free equipment to county clinic for telemedicine encounters related to HIV prevention
  - OIG: AKS implicated but no sanctions
DHS Background Studies

- Minnesota requires background studies by DHS for any person providing “direct contact” services in a licensed program
- "Direct contact" means providing face-to-face care, training, supervision, counseling, consultation, or medication assistance to people served in health and human service programs
- DHS representatives have stated that telemedicine providers must have a study (and be fingerprinted)

Patient consent

- Some states require special consent
- Additional issues to consider
  - Providing names, credentials, and associations of all health care providers involved
  - Description of technology used in encounter
  - Risks specific to electronic nature of care delivery (e.g., lost connection, limitations of technology)
  - Security and privacy issues and precautions
  - Plan for ongoing care, location of health records
  - Prescribing limitations
  - Alternatives to telemedicine encounter
Miscellany

- Section 1557
- FDA issues for digital health – is it a device?
- Parity laws
- Medicare billing

Thank you!

Paul Harris  Katie Ilten
New and Emerging Benefit Models: How to Get to Implementation Beyond the Regulatory Chaos

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New and Emerging Benefit Models
How to Get to Implementation Beyond the Regulatory Chaos

Key Authorities

Presidential Executive Orders

- Executive Order 13765, “Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal” (Jan. 20, 2017)


Short-term, Limited Duration rules:

  - 26 C.F.R. § 54
  - 29 C.F.R. § 2590
  - 45 C.F.R. § 144
  - 45 C.F.R. § 146
  - 45 C.F.R. § 148

Association Health Plan (AHP) rules:

- 83 Fed. Reg. 28912 (June 21, 2018)
  - 29 C.F.R. § 2511


Minnesota Statutes, section 62A.65, subdivision 7 – Short-Term Medical

Chapter 62H of the Minnesota Statutes, AHPs

Timeline of Relevant Events

January 20, 2017 – President Trump takes office, issues Executive Order 13765


May 4, 2017 – AHCA passes U.S. House

June 22, 2017 – Better Care Reconciliation Act (“BCRA”) introduced in U.S. Senate

July 25, 2017 – BCRA fails to move forward

July 27, 2017 – Health Care Freedom Act (“HCFA”) (so-called “skinny repeal”) voted down in the U.S. Senate

September 2017 – Graham-Cassidy not advanced in the U.S. Senate

October 12, 2017 - Executive Order 13813

January 5, 2018 – Association Health Plan (“AHP”) Proposed Rule published

February 21, 2018 – Short-term, Limited Duration Proposed Rule published

June 21, 2018 – AHP Final Rule promulgated

August 3, 2018 – Short-term, Limited Duration Final Rule promulgated

March 28, 2019 – Federal district court (District of D.C.) vacates much of AHP Final Rule

April 26, 2019 – U.S. Department of Labor appeals district court order
Hot Topics for Medical Staff Leaders and Counsel Who Advise Them

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I. INTEGRATION OF ADVANCED PRACTICE PROVIDERS (APPS) INTO THE MEDICAL STAFF

A. BACKGROUND

APPs are playing an increasingly significant role in patient care and organizational leadership at many hospitals. Particularly in rural areas, APPs often comprise a majority of a hospital's healthcare providers and may be the only providers in the community on a daily basis. The Association of American Medical Colleges projects a physician shortage of up to 120,000 physicians by 2030 while the APP workforce is rapidly growing, with the number of licensed nurse practitioners more than doubling from 2007 to 2017. With demographers projecting that an aging population will drive a greater need for preventive and geriatric care, APPs will likely fill many of the gaps. At the same time, APPs, particularly advanced practice registered nurses, are gaining independent practice rights in many states. This combination of circumstances is causing many hospitals to consider whether APPs should be integrated as members of the hospital's medical staff.

B. LICENSURE AND SCOPE OF PRACTICE

1. Advanced Practice Registered Nurse (APRN) – scope and practice standards are defined by national professional nursing organizations specific to the APRN's category and population focus.\(^1\)

   a) Four categories of APRNs:

      (1) Nurse Practitioner (CNP)

         (a) Scope of Practice: Health promotion and education, health assessment and screening, diagnosing, treating and facilitating patient management of acute and chronic diseases, ordering, performing and interpreting diagnostic studies (except for CT, MRI, PET, nuclear scans and mammography), and prescribing pharmacologic and non-pharmacologic therapies.

         (b) Patient population: Depends on population focus.

      (2) Clinical Nurse Specialist (CNS)

         (a) Scope of Practice: Diagnosis and treatment, disease management, prescribing pharmacological and non-pharmacological therapies, ordering, performing and interpreting diagnostic studies (except for CT, MRI, PET, nuclear scans and mammography), education, and integration of care.

         (a) Patient population: May treat individuals, families and communities, depending on population focus.

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(3) Nurse-Midwife (CNM)

(a) Scope of Practice: Women's primary health and gynecological care (including pregnancy, childbirth, and postpartum), care of newborn, family planning, partner care management related to sexual health, ordering, performing and interpreting diagnostic studies, and prescribing pharmacologic and non-pharmacologic therapies.

(b) Patient population: Generally limited to caring for women and newborns.

(4) Registered Nurse Anesthetist (CRNA)

(a) Scope of Practice: anesthesia care and related services including selecting, obtaining and administering drugs and therapeutic devices, ordering, performing and interpreting diagnostic studies (except CT, MRI, PET, nuclear scans and mammography), prescribing pharmacologic and non-pharmacologic therapies. Also includes nonsurgical therapies for acute and chronic pain in collaboration with a physician.

(b) Patient population: Broad, may depend on population focus and collaboration arrangement with physician.

b) Each APRN must have one or more of the following population foci:

(1) Family and individual across the life span;
(2) Adult gerontology;
(3) Neonatal;
(4) Pediatrics;
(5) Women's and gender-related health; or
(6) Psychiatric and mental health.

c) General licensure qualifications:

(1) Hold a current license as an RN in Minnesota or demonstrate eligibility for licensure.
(2) Complete a graduate (master's or doctoral) level accredited APRN program.
(3) Certification by a national nursing certification organization recognized by the Minnesota Board of Nursing.

d) Each APRN is accountable: (a) to patients for the quality of care rendered; (b) for recognizing limits of knowledge and experience;
and for planning for the management of situations beyond the APRN's expertise.

e) With limited exceptions, APRNs may practice independently.\(^2\) No supervision or collaboration agreement with a physician is required.

2. **Physician Assistant (PA)\(^3\)**

a) **Scope of Practice:** The duties and responsibilities delegated in the physician – PA delegation agreement including the prescribing, administering, and dispensing of drugs, controlled substances, and medical devices, excluding certain anesthetics. Patient services must be limited as follows:

(1) Services within the training and experience of the PA;

(2) Services customary to the practice of the supervising physician;

(3) Services delegated under the physician – PA delegation agreement; and

(4) Services within the parameters of the laws, rules and standards of the facilities in which the PA practices.

b) **Physician – PA Delegation Agreement**

(1) Required for all PAs.

(2) A document prepared and signed by the physician and PA that affirms the supervisory relationship and defines the PA's scope of practice, including describing:

   (a) The means of supervision;

   (b) The specific categories of drugs, controlled substances, and medical devices that the supervising physician delegates to the PA to prescribe.

(3) Delegated services may include:

   (a) Taking patient histories and developing medical status reports;

   (b) Performing physical examinations;

   (c) Interpreting and evaluating patient data;

   (d) Ordering or performing certain diagnostic or therapeutic procedures;

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\(^2\) The primary exceptions are CRNAs providing nonsurgical therapy for acute or chronic pain and CNPs and CNSs in their first 2,080 hours of practice.

\(^3\) Minn. Stat. ch. 147A.
(e) Providing instructions regarding patient care, disease prevention, and health promotion;

(f) Assisting the supervising physician in patient care in home and health care facilities;

(g) Creating and maintaining appropriate patient records;

(h) Transmitting or executing specific orders at the direction of the supervising physician;

(i) Prescribing, administering, and dispensing drugs, controlled substances, and medical devices;

(j) Assisting at surgery; and

(k) Providing medical authorization for admission for emergency care and treatment.

c) General licensure qualifications:

(1) Completion of a graduate (master's) level education program; and

(2) Certification by the National Commission on Certification of Physician Assistants.

C. KEY CONSIDERATIONS IN APP INTEGRATION

1. **Eligibility** – Which APPs will be medical staff members? Both APRNs and PAs? Just APRNs based on independent practice rights? Only certain APRNs based on the hospital's need and patient population?

   a) In multi-state systems, be mindful of differences in scope of practice based on state licensure laws.

2. **Membership Category** – Will APPs be full members of the relevant medical staff category? Will APPs be in a separate category with more limited rights? How will the increasing educational attainment and scope of practice of APPs, particularly APRNs, affect the likelihood of a legal challenge to disparate treatment of APPs and physicians.

3. **Voting** – Will APPs have full voting rights?

4. **Committees** – Will APPs be permitted to serve on all committees? Are there committees that should be staffed only by physicians?

5. **Privileging** – Privileging of APPs must be consistent with licensure, certification, scope of practice, and population focus.

6. **Peer Review** – Who is a peer?

   a) Will APPs have the same fair hearing rights as physicians?

   b) Unlike physicians, the NPDB does not generally require reporting on APPs.
c) Who will comprise the hearing panel for an APP?
d) Physicians? APPs with the same license? A mix?
e) Will APPs be permitted to sit on hearing panels for physicians?
f) What is the appropriate role for the supervising physician, if applicable, in FPPE and OPPE?

7. Leadership Positions – Will APPs be eligible for medical staff leadership positions?

II. ADDRESSING THE OPIOID EPIDEMIC

A. MINNESOTA OPIOID PRESCRIBING IMPROVEMENT PROGRAM ("OPIP")

Due to the opioid epidemic Minnesota, like many states, has taken legislative action to monitor and address the perceived overprescribing of opioids by healthcare providers. One aspect of this monitoring specifically targeted at opioid prescribing is OPIP.

1. Goal is to "reduce opioid dependency and substance use by Minnesotans due to the prescribing of opioid analgesics by health care providers."4

a) Recommended by a multi-disciplinary opioid prescribing work group.5

b) Includes the following opioid prescribing sentinel measures as benchmarks for providers:

(1) Rate of prescribing first opioid prescriptions after 90 days of opioid naiveté (an "index opioid prescription").6

(2) Rate of prescribing an index opioid prescription over the recommended dose.

(3) Rate of prescribing more than 700 cumulative morphine milligram equivalents (MME) during the acute and post-acute pain period.

(4) Rate of prescribing chronic opioid analgesic therapy.

(5) Rate of prescribing high-dose (≥ 90 MME per day) chronic opioid analgesic therapy.

(6) Rate of prescribing concomitant opioid and benzodiazepine therapy.

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4 Minn. Stat. § 256B.0638, subd. 1.
5 Minn. Stat. § 256B.0638, subd. 3.
6 A patient who is opioid naïve is one who does not have "an active opioid prescription in the 90 day period prior to the index opioid prescription." Sentinel Opioid Prescribing Measures, Minnesota Department of Human Services, available at https://mn.gov/dhs/opip/quality-improvement-program/measures/ (May 22, 2019).
Percent of patients on chronic opioid analgesia therapy who receive opioids from multiple providers.\textsuperscript{7}

c) The Minnesota Department of Human Services will provide individualized opioid prescribing reports based on Medicaid and MinnesotaCare administrative claims data to all health care providers who prescribe opioids for pain management and treat patients enrolled in MinnesotaCare or Medical Assistance.\textsuperscript{8}

d) Providers whose opioid prescribing pattern exceeds the opioid quality improvement standard thresholds are required to submit a quality improvement plan for review by DHS with the goal of aligning the provider's prescribing practices with community standards.\textsuperscript{9}

e) If a provider's opioid prescribing pattern fails to improve, DHS may (a) monitor the provider's prescribing practices more frequently than annually; (b) monitor more aspects of the provider's prescribing than the sentinel measures; (c) require additional quality improvement efforts, including use of the prescription monitoring program; or (d) terminate the provider from all Minnesota health care programs (MinnesotaCare and Medical Assistance).\textsuperscript{10}

2. Medical staffs may want to consider incorporating the opioid prescribing sentinel measures into their quality standards and monitoring the prescribing practices of all providers prescribing opioids for consistency with community standards.

a) Other resources that may be useful include the Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain published by the Centers for Disease Control and Prevention and Stem the Tide: Addressing the Opioid Epidemic published by the American Hospital Association.\textsuperscript{11}

3. If a provider is placed on additional monitoring or quality improvement efforts by DHS, the medical staff may want to consider implementing FPPE

\textsuperscript{7} Id.

\textsuperscript{8} Opioid Prescribing Reports, Minnesota Department of Human Services, available at https://mn.gov/dhs/opip/quality-improvement-program/reports/ (May 22, 2019).

\textsuperscript{9} Minn. Stat. § 256B.0638, subd. 5.

\textsuperscript{10} Minn. Stat. § 256B.0638, subd. 5. We note that termination of a provider from all Minnesota health care programs would likely be an event reportable to the National Practitioner Data Bank.

with respect to that provider's prescribing practices consistent with or in addition to the DHS measures.

B. MANAGING IMPAIRED PROVIDERS

Unfortunately, health care providers are not exempt from the disease of opioid addiction and face unique risks due to their proximity to opioids as part of their work environment. Many medical staff impaired provider policies, often designed with alcohol addiction or physical disability in mind, do not fully address issues that may arise from a provider who is impaired as a result of opioid abuse and/or addiction. Additionally, not all medical staff bylaws and policies are well tailored to take advantage of HPSP and similar resources to facilitate a recovering provider's return to practice.

1. Impaired Provider Policy Issues to Consider
   a) Anticipated timeline of opioid treatment programs and follow-up monitoring compared to timeframes specified in the impaired practitioner policy;
   b) Criteria and duration of follow-up monitoring;
   c) Impact of work-site monitoring and required supervision on provider's authority to exercise privileges;
   d) Impact of pharmacotherapy, both opioid substitution therapy (methadone or buprenorphine) and non-opioid maintenance therapy (naltrexone), on the provider's ability to safely resume practice;
   e) Access to controlled substances upon returning to practice; and
   f) Manner of addressing relapse(s).

2. Reporting Obligations
   a) Note that employers and health care institutions are generally required to report to the applicable licensing board if the employer/institution has knowledge that a provider has diverted narcotics or other controlled substances from the employer/institution.\textsuperscript{12}

3. Minnesota Health Professionals Services Program (HPSP)\textsuperscript{13}
   a) Available to health care providers who are unable to practice with reasonable skill and safety by reason of illness, use of alcohol, drugs, chemicals, or any other materials, or as a result of a mental, physical, or psychological condition.
      (1) Health care providers are not eligible if they (i) diverted controlled substances for other than self-administration; (ii) have previously been terminated from HPSP or a similar

\textsuperscript{12} Minn. Stat. § 214.33, subd. 5.
\textsuperscript{13} Minn. Stat. §§ 214.31 – 214.37
program in another state; (iii) are currently under a board disciplinary order or corrective action agreement, unless referred by the board; (iv) have been diagnosed with HIV, hepatitis B, or hepatitis C, unless referred by the board; (v) have been accused of sexual misconduct; or (vi) would create a serious risk of harm to the public through continued practice.

b) HPSP typically:

(1) Refers providers to qualified professionals for evaluation, treatment and development of a written plan for continuing care.

(2) Enters into individualized program participation agreements between providers and the program that may include a continuing care plan, practice monitoring, health monitoring, practice restrictions, random drug screening, support group participation, filing of reports necessary to document compliance, and definition of successful completion of the program.

c) HPSP is an alternative to board reporting and discipline for qualified providers who are impaired due to substance abuse, illness, or other conditions and for whom no aggravating circumstances are present (i.e., patient harm, other violations of the applicable practice act).

(1) A provider that fails to comply with the terms of his or her HPSP participation agreement will be referred to the applicable licensing board for appropriate action.

d) Reporting to HPSP generally fulfills the reporting obligations of licensed providers under their applicable practice acts.

e) Medical staffs should consider requiring enrollment in HPSP and compliance with the HPSP program participation agreement as part of an impaired provider's return to work.

III. 2018 CHANGES TO THE ADVERSE CLINICAL ACTION REPORTING PROVISIONS OF THE NATIONAL PRACTITIONER DATA BANK GUIDEBOOK

A. BACKGROUND

In 1986, in an attempt to improve the quality of health care, discourage the practice of incompetent practitioners moving from one hospital to another when they ran into problems, and protect medical staff members who engaged in good-faith peer review, Congress passed the Healthcare Quality Improvement Act of 1986. The law provided both a carrot and a stick for hospital medical staffs engaged in practitioner peer review. The carrot was a provision that granted immunity from damages to medical staff members and other participants in the peer review process, as long as the

14 42 USC § 11101 et seq.
peer review was taken in good faith and in a reasonable belief that it was in furtherance of quality health care, and appropriate due process was provided to the affected practitioner.\textsuperscript{15} The stick was that the law enabled the establishment of a new national data bank, the National Practitioner Data Bank ("NPDB") intended to be a national clearinghouse for healthcare entities to report and access adverse quality information about practitioners. Hospitals and their medical staffs and other peer review participants could lose the new protections if they failed either to report to or query the Data Bank when the law required it.\textsuperscript{16}

In 2001, the Health Resources and Services Administration ("HRSA"), which administers the NPDB, published the first NPDB Guidebook, an attempt to make the reporting and querying portions of the law more user-friendly, to provide answers to some tricky questions under the HCQIA, and to function as a resource for medical staffs. Although the Guidebook is not promulgated as a regulation, but rather intended as a policy manual, it has become a significant resource to practitioners in the area. While it was not an official rule-making process, a draft of the 2015 amendments was circulated for comment before it was finalized.

Since its inception, the NPDB has been a mixed blessing for medical staffs. On the one hand, medical staffs appreciated the granted immunity, as well as an increased ability in the credentialing process to obtain qualitative information about prospective medical staff members through a Data Bank query. On the other hand, medical staff leaders experienced a great deal of pressure when considering taking actions to address quality or conduct concerns relating to an individual medical staff member, since the consequences for the individual practitioner of a Data Bank report went far beyond the historical consequences of simply losing privileges at a local hospital.

In many cases, there was a natural reluctance to incur the time and expense inherent in providing the type of due process required to comply with the provisions of the HCQIA. As a result, many hospital medical staffs began to take advantage of perceived loopholes in the law and used these processes as leverage to negotiate resolutions that would permit them to quietly rid themselves of problematic practitioners without having to file a Data Bank report, or at a minimum to delay the necessity of a report as long as possible. For example, the term "summary suspension" was identified as an action that adversely affects the clinical privileges of a practitioner, thus triggering a report if it lasted for more than 30 days. Subsequently, some medical staffs developed a concept of "precautionary suspension," and decided that this type of suspension was not reportable. The processes were virtually indistinguishable, except that the bylaws usually contained language to the effect that the precautionary suspension was being imposed "in order to determine whether" there was a risk to patient safety, as opposed to being "necessary in order to prevent grave harm to patients" (i.e., more typical summary suspension language). The officials at the NPDB were not impressed. The 2015 Guidebook stated that "An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action."\textsuperscript{17}

The Guidebook addresses all aspects of the NPDB, but particularly relevant for hospital medical staffs is the requirement to report "adverse professional review actions." The applicable statutory

\textsuperscript{15} 42 USC § 11111(a)
\textsuperscript{16} 42 USC § 11111(b)
language interpreted by the NPDB Guidebook with respect to medical staff adverse professional actions is as follows:

"Each health care entity which -

(A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;

(B) accepts the surrender of clinical privileges of a physician -

(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or

(ii) in return for not conducting such an investigation or proceeding; or

... shall report to the Board of Medical Examiners, in accordance with section 11134(a) of this title, the information described in paragraph (3)." 18

This definition is important, because the authors of the Guidebook have significantly expanded the concepts of an "investigation" and "in return for not conducting such an investigation"19 in the past two revisions to the Guidebook, arguably beyond the statutory language. The original 2001 NPDB Guidebook was amended for the first time in 2015, a relatively comprehensive update. Perhaps the two most significant elements of that update were a great expansion of the term "investigation"20 and the introduction of the concept that a practitioner did not need to even be aware that an investigation was underway in order for a resignation or surrender of privileges by the practitioner to constitute a reportable event.21 Prior to the 2015 update, many medical staffs sought to avoid premature or potentially unfair reporting by defining the term "investigation" very narrowly in their bylaws. The 2015 update made it clear that these definitions were not dispositive. The insistence that resignation by a practitioner who does not even know she is under investigation is reportable strays rather far from the concept of resignation "in return for not conducting such an investigation or proceeding," which would seem to imply some quid-pro-quo.

More recently, in October 2018, HRSA issued another update in which it sought to further clarify and narrow the circumstances under which a hospital could avoid reporting the resignation or other surrender of privileges by a practitioner. Not only did HRSA double down on the notion that the practitioner's awareness of an investigation was not a requirement to trigger reporting, they seemed to expand even further the conduct that could be deemed to be an "investigation."22

18 42 USC § 11133(B)(ii)
19 The Guidebook authors have shortened this to "in order to avoid." See, e.g.,
20 Guidebook, April 2015 Edition, p. E-34, stating that "if a formal, targeted process is used when issues related to a specific practitioner's professional competence or conduct are identified, this is considered an investigation for purposes of reporting to the NPDB." (Emphasis in the original.) Also: "For NPDB reporting purposes, the term "investigation" is not controlled by how that term may be defined in a health care entity's bylaws or policies and procedures."
21 See, e.g, Guidebook April 2015 Edition, page E-45, in the answer to Question 18, wherein it is stated, "A practitioner's awareness of an investigation is being conducted is not a requirement for reporting to the NPDB."
22 See, e.g., Guidebook October 2018 Edition, page E-50, suggesting that if during the process of reappointment, the credentials committee had "specific concerns" about a practitioner, the review of the reappointment application might be seen as an investigation, such that a withdrawal of the application might be reportable.
B. THE 2018 AMENDMENTS:

The 2018 Amendments accomplished the following:

1. Modified language regarding the obligation to report a proctoring requirement, clarifying that whether a proctoring requirement must be reported depends upon whether a proctor is required in order for a practitioner to proceed in freely exercising clinical privileges, and whether the period in fact lasts longer than 30 days. As before, if proctoring consists only of retrospective review, this is not considered reportable.

2. Added a new section entitled, "Length of Restriction." The point of this section is to clarify when a restriction must be reported when it is not evident at the time the restriction is imposed whether it will continue for more than 30 days. This appears to be in response to a 2017 federal court decision finding a proctoring restriction was not reportable because it was not clear at inception that the proctoring would take more than 30 days. The reporting requirement requires a report if an adverse professional review action "adversely affects" the clinical privileges for longer than 30 days. This new section clarifies that the NPDB has consistently interpreted "adversely affects" to mean the impact of the restriction, not how it was written. Therefore, if a proctoring requirement is imposed for "the next 60 procedures," whether that is reportable depends on when the practitioner actually completes the required number of procedures. If the practitioner does 60 procedures in 29 days, and is approved to return to full practice, no report is required. If the same requirement takes 31 days, it must be reported. An "indefinite" suspension is not necessarily reportable; it depends on whether it is, in fact, in effect for more than 30 days.

3. Added seven new Questions and Answers to the end of Chapter E, the section on Reporting Adverse Clinical Privileges Actions, with the following information:
   
a) Q & A 22: So-called "voluntary" agreements not to exercise privileges during an investigation (which are frequently anything but) are reportable.

b) Q & A 23: Leaves of absence while under investigation are reportable, "to the extent a leave of absence restricts a practitioner's ability to exercise privileges." By contrast, if privileges "remain intact" during the leave, then the leave is not reportable.

c) Q & A 24: Withdrawal of an application for reappointment or resignation during the pendency of review of a reappointment application may be reportable if the review by the credentials.

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24 id.
committee of certain concerns rises to the level of an "investigation," i.e., is not "routine."

d) Q & A 25: A practitioner who is subject to a "quality improvement plan" may be subjected to reporting under two different scenarios. First, if the quality improvement plan restricts in any way the practitioner's ability to exercise privileges, is the result of a professional review action, concerns the practitioner's professional competence or conduct, and lasts more than 30 days, it is reportable. Second, if the quality improvement plan is imposed due to specific competency concerns about an individual practitioner, and is of the type that typically leads to a professional review action, then this could be considered an "investigation," and a resignation of the practitioner while subject to this plan would be reportable. This is distinguishable from routine Focused Professional Practice Evaluations ("FPPE") that are imposed on all new medical staff members, for example.

e) Q & A 31: Whether a requirement that a surgeon operate only with a qualified first assistant is reportable depends on the facts and circumstances. If it's a part of a routine requirement imposed on all similarly-situated surgeons, then no. But if the surgeon is singled out, the requirement arises out of a professional review action about professional competence and conduct, and the requirement runs more than 30 days, then it is reportable.

f) Q & A 46: If a practitioner's privileges lapse at a time when the practitioner is under investigation, and the practitioner elects not to renew, the non-renewal is reportable as a resignation of privileges while under investigation.

g) Q & A 49: If a judicial decision modifies or reverses a professional review action taken by a hospital that has been reported to the NPDB, the hospital should either report a revision to the original report (modification) or void the original report (reversal).

4. The new questions and answers continue to make it clear that the hospital is obligated to report a resignation, non-renewal or leave of absence while a practitioner is under investigation, even if the individual did not know they were under investigation.27

C. PRACTICE TIPS:

1. As an initial matter, the philosophy of the medical staff and institution involved may dictate what, if any, steps will be taken to address risk under the current Guidebook guidance. An extremely physician-friendly hospital/medical staff may want to take further steps to avoid reporting as much as possible, while others may be grateful for the clarity and simply accept the new state of affairs.

2. For proctoring and similar requirements to be imposed based on the number of procedures performed, consider providing for an intermediate review at Day 28 or 29, with the possibility of lifting the requirement if the number is close and the results look good.

3. Instead of the traditional medical staff bylaw approach of trying to narrow the definition of an "investigation," which HRSA has indicated it won't honor anyway, consider adopting an expansive definition and then adding a notice requirement. This may be a difficult idea to implement because of the liability risks inherent in the approach.

4. Somewhat contrary to #3, above, clarify when focused reviews and recredentialing reviews are considered routine, and what developments take them out of the routine realm. This would be an attempt to still protect the early stages of evaluating a practitioner from being defined as an "investigation."

5. Develop a leave of absence approach that does not technically restrict privileges and use that process when a problem develops. Practitioners could be "encouraged" to take a leave of absence, but with the caveat that they could return at any time on 24 hours "administrative" notice. Of course, it's hard to see a difference between this and a "voluntary" agreement not to exercise privileges. It also provides risk for the hospital if a dangerous practitioner can return to exercising privileges based on a unilateral, and fairly short-term, notice.

6. Refrain from outlining "next steps" when imposing a quality improvement plan or FPPE. The Guidebook suggests that "or else" language heightens the suspicion that the quality plan is really an investigation.
Drug Price Policy and Other Key Developments Affecting Drug Costs

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DRUG PRICE POLICY
AND OTHER KEY DEVELOPMENTS AFFECTING DRUG COSTS

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June 20, 2019

Agenda
► Background
  ► Drug Distribution System Today
  ► Drug Pricing Trends
► Legislative and Regulatory Reforms
  ► Transparency
  ► Prescription Drug Benefits
  ► Rebates
  ► Drug Price Negotiation
  ► Generic Competition
  ► Importation
► Q&A

*Materials gathered as of May 22, 2019
BACKGROUND

Drug Distribution Overview (Simplified)

Drug Manufacturers/Wholesalers

- Purchase Contract (Discounts)
- Rebates/Data Fees

Pharmacies (including mail order)

- Admin Fees/Claim Funds
- Rebates

PBM

- Pharmacy Benefit Contract
- Insurance Contract
- Premiums

Payors (Gov’t, Health Plans, Employers)

- Insurance Premiums

Members/Consumers

- Drug Price/Copay

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Rising Drug Costs

► Prescription drug spending is growing 6.1 percent annually, compared with 5.5 percent growth for overall national health expenditures
► Growth in spending stems from new brands, high prices for existing drugs (particularly for specialty drugs) and fewer patent expiries

Graph provided by BGOV OnPoint: Drug Pricing Proposals (May 2, 2019)


Rising Drug Costs

► Prescription drug trend has slowed recently but remains high for specialty drugs
► Among commonly used specialty drugs, branded drug prices have increased by 57% since 2014; comparatively, prices for generic drugs dropped by 35% since 2014

LEGISLATIVE & REGULATORY REFORMS

AS OF MAY 22, 2019

Legislative & Regulatory Reforms (Overview)

► Transparency
► Prescription Drug Benefits
► Rebates
► Drug Price Negotiation
► Generic Competition
► Importation
Transparency: Federal Action

► Direct-To-Consumer (DTC) Final Rule
► Requires drug manufacturers to disclose list prices of certain drugs in DTC television advertisements.
► Applies to drugs covered by Medicare and Medicaid with a wholesale acquisition cost (WAC) equal to or greater than $35 per month for a 30-day supply or the typical course of treatment.
► Goals:
  ► Incent manufacturers to reduce list prices by exposing overly costly drugs to public scrutiny; and
  ► Provide consumers with information to better position themselves as active and well-informed participants in their healthcare decision-making.
► Effective July 9, 2019

Transparency: Federal Action

► Part D Final Rule
► Real-Time Benefits - Requires Part D sponsors to implement a real-time benefits tool (RTBT) to provide formulary and patient-specific benefit information to at least one prescriber.
► Explanation of Benefits (EOBs) – Part D sponsors must include drug price increase (if applicable) and lower cost alternatives information.
► ‘Gag Clauses’ – Implements statutory prohibition on contractual provisions prohibiting or penalizing disclosure of lower priced options.
► Price Concessions - CMS considered, but did not finalize, changes requiring Part D plans to report to CMS the lowest possible price that could be paid to the pharmacy.
► Effective January 1, 2021
► Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, (final rule filed May 16, 2019 and scheduled for publication May 23, 2019).
Transparency: Federal Proposals

► Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act (S. 637) would require public disclosure of rebate information for MA and QHP plans
  ▶ Sponsored by Sen. Wyden (D – OR); 4 co-sponsors (all Dems)
    ▶ Included in Senate Finance Committee review by Sen. Grassley (R – IA)
  ▶ Requires PBMs to report to HHS (1) amount and type of rebates and discounts negotiated for each MA and QHP plan and (2) extent to which they are passed on to plan sponsors.
  ▶ Also requires PBMs to report the difference between the amount paid to the PBM by a plan sponsor and the amount paid to pharmacies by the PBM.
  ▶ Further requires PBMs to pass through to plan sponsors a minimum percentage (as determined by HHS) of rebates and discounts attributable to member utilization.
  ▶ In House, Prescription Drug STAR Act (HR 2113) has limited bipartisan support and requires PBMs to disclose all rebates and price concessions by drug class in the aggregate to HHS for public reporting.

Transparency: State Laws

► California: SB 17 Health Care: Prescription Drug Costs
  ▶ Imposes significant reporting requirements on drug manufacturers and health plans.
  ▶ Goal: Increase drug cost transparency by
    ▶ Requiring 60-day advance notification to public and private purchasers before a significant (16%) prescription drug WAC increase, and making public certain information associated with the increase; and
    ▶ Requiring managed care plans and insurers to report the top 25 most expensive drugs, top 25 drugs with highest year-over-year increase in total spending, and impact of drug costs on premiums.
  ▶ Information published online at oshpd.ca.gov, CDI, and DMHC websites.
  ▶ Creates incentive for manufacturers to increase prices just below the disclosure threshold.
Transparency: State Laws

Washington: SHB 1224 Concerning Prescription Drug Cost Transparency

► Enacted May 9, 2019, with reporting beginning October 1, 2019.
► Reporting requirements for manufacturers, PBMs and health insurers:
  ► Manufacturers: 60-days advance notice of price increases for medications with wholesale cost over $100 for less than month’s supply and that have an increase of 20% over one year or 50% over three years
  ► PBMs: all discounts and rebate received from manufacturers, including amounts retained by the PBM; pharmacy reimbursement amounts (after fees); and ownership interests in plans or pharmacies with which is does business
  ► Health Insurers: reporting requirements similar to those in California SB 17

Prescription Drug Benefits: Parts B and D

► May 2019 Final Rule codified ability for Medicare Advantage plan sponsors to apply step therapy to Part B Drugs (with guardrails)
  ► Followed up on an August 7, 2018 memo permitting step therapy for January 2019.
  ► CMS proposed, but did not finalize, allowing step therapy, prior authorization, indication-based formularies, and increased utilization management flexibility within Part D protected classes.
  ► Codified existing guidance allowing step therapy and prior authorization for 5 of 6 protected classes for new drug treatments.

► Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, (final rule filed May 16, 2019 and scheduled for publication May 23, 2019).
Prescription Drug Benefits: PBMs

► Majority of states have enacted or are considering enhanced oversight authority over PBMs, including PBM licensure or regulation.
  ► MN law adopted on May 17, 2019
  ► NCOIL PBM Licensure and Regulation Model Act adopted December 2018
    ► Requires PBMs to obtain a license with the state department of insurance (DOI)
    ► Prohibits “gag clauses”
    ► Encourages states to provide DOI with authority to adopt regulations relating to other matters, including:
      ► PBM network adequacy;
      ► Rebate transparency;
      ► Pharmacy reimbursement processes and requirements;
      ► Procedures for pharmacy audits conducted by or on behalf of PBMs;
      ► Affiliated PBM/pharmacy information sharing restrictions

► NAIC PBM Work Group
  ► Charged with developing a PBM Model Regulation
  ► Work plan being developed

► States also considering other PBM measures, including:
  ► Rebate and network pharmacy discount reporting requirements
  ► Prohibitions on ‘gag clauses’ and ‘claw-backs’
  ► Imposing fiduciary-like duties

► https://www.naic.org/cmte_b_pharmacy_bmri_sg.htm
Rebates: Federal Proposals

- Proposed rule issued in January 2019 would significantly alter existing rebate system with respect to Medicare and Medicaid programs
  - Eliminates the current safe harbor for manufacturer rebates under federal anti-kickback laws
  - Replaces existing safe harbor with two new safe harbors:
    - Up-front rebate amounts that are ‘completely’ applied at the point-of-sale (e.g., through pharmacy chargebacks with the manufacturer)
    - Fixed-fee service arrangements between manufacturers and PBMs not based on utilization
  - Proposed rule does not apply to commercial plans
    - Senate bill (S. 657) would require commercial plans to comply with new safe harbors
  - Subsequent CMS guidance issued regarding 2020 bids and possible two-year risk corridor demonstration pilot


Rebates: Federal Proposals

- Prescription Drug Rebate Reform Act
  - Introduced by Mitt Romney (R – UT) and Mike Braun (R – IN)
  - Would require group health plans and health insurance issuers offering group or individual coverage to set coinsurance obligations for covered prescription drugs based on percentage of “net price” rather than list price.
  - “Net price” means the list price of a drug net all rebates, discounts, concessions, and other adjustments applied to the cost paid by the group health plan or health insurance issuer, or by any other entity that provides pharmacy benefit management services under a contract with such group or issuer, regardless of whether such adjustments are prospective or retrospective.
Drug Price Negotiation: Federal Proposals

► Medicare Drug Price Negotiation Act (S. 99) would direct HHS to negotiate prices for drugs covered under Medicare Part D
  ► Sponsored by Sen. Sanders (I – VT); 7 co-sponsors (all Dems)
  ► Would strike “noninterference clause” prohibiting HHS negotiations and formularies
  ► HHS would negotiate with drug makers on prices, including discounts and rebates, that can be charged for Part D drugs
    ▶ If negotiations aren’t successful, price would be based on those set for other federal programs or based on prices in five specified countries
    ▶ HHS would prioritize drug negotiations based on total expenditures, spending per beneficiary, out-of-pocket thresholds, and other factors
  ► Other provisions would:
    ▶ Direct HHS to establish single drug formulary with at least two drugs in each category
    ▶ Require drug-makers to provide rebates to HHS to pass through for low-income individuals

Drug Price Negotiation: State Proposals

► Maryland: H.B. 768 Prescription Drug Affordability Board
  ► Creates a panel to review prescription drug prices and cap the price at which public agencies pay for those drugs
  ► Applies only to plans providing coverage to county and state government employees
  ► Unless vetoed by Governor, will take effect on July 1, 2019 with phased rollout:
    ▶ By December 31, 2020, the Board must study the pharmaceutical distribution and payment system and policy options used in other states and countries, submit findings, and make recommendations.
    ▶ By July 1, 2021, if the study results in a recommendation that the state impose upper payment limits on drugs, then the Board must submit a plan of action
    ▶ On or after January 1, 2022, if the plan of action is approved, then the Board may begin to set upper payment limits, and must study the impact of such actions on the availability of drugs.
    ▶ By December 1, 2023, if the plan of action was implemented, then the Board must report to the Assembly and advise whether its authority should be expanded to all purchases and payer reimbursements statewide.
### Generic Competition: Federal Proposals

**► CREATE Act (S. 974)**
- Supporters include Sens. Patrick Leahy (D – VT) and Charles Grassley (R – IA)
- Goal: Increase the speed that a generic drug can get to market
- Require brand drug makers to sell "sufficient quantities" at "commercially reasonable" prices to generic competitors who need samples for bio-equivalency testing
- Establish a legal framework for generics to get injunctive relief from courts, and allow judges to award payments to generic drug makers.

**► REMEDY Act (S.1209)**
- Introduced by Sens. Dick Durbin (R – IL) and Bill Cassidy (R – LA)
- Removes incentives for drug manufacturers to file additional patents to extend monopolies (“evergreening”) past the 20-year patent term.


### Generic Competition: Federal Proposals

**► Protecting Access to Biosimilars Act (S.1140)**
- Cosponsored by Sens. Bill Cassidy (R – LA) and Tina Smith (D – MN)
- Response to FDA’s 2018 announcement that it would begin regulating insulin as a biologic drug in 2020
- Would codify the FDA’s promise that insulin makers would not be granted the 12 years of exclusivity provided for new biologics, since the products have already been approved.

**► Ensuring Timely Access to Generics Act (S.1169)**
- Cosponsored by Sens. Bill Cassidy (R – LA) and Cory Gardner (R – CO)
- Would enable the FDA to reject citizen petitions to delay entry of generics where the agency concludes that the petition’s primary purpose is to delay a generic drug application’s approval
Importation: Federal Action

► Affordable and Safe Prescription Drug Importation Act (S. 97) would allow wholesalers, pharmacists, and patients to import drugs
  ► Sponsored by Sen. Sanders (I – VT); 22 co-sponsors (Dems and one Independent)
  ► Qualifying prescription drugs would have to be approved for use in Canada
  ► HHS could permit imports from other countries with comparable standards if it finds imports from Canada led to cost savings and increased access
  ► Prohibitions or limitations on certain drugs, such as controlled substances, anesthetic drugs inhaled during surgery, compounded drugs, biologics, and products with safety protocols
  ► Foreign sellers would have to be certified by the FDA and pay fees
    ▶ Drug-makers could not restrict drugs to foreign sellers
    ▶ New penalties for online pharmacies that sell adulterated or counterfeit drugs or that dispense to someone without a valid prescription

► Also see Safe and Affordable Drugs from Canada Act of 2019 (S. 61)
  ► Sponsored by Sen. Grassley (R – IA) and Sen. Klobuchar (D – MN)
  ► Would allow personal importation of drugs from approved pharmacies in Canada

Importation: State Action

► Florida: H.B. 19 Prescription Drug Importation Programs
  ► Passed the Florida House and Senate on April 29, 2019
  ► Enables importation of selected drugs from Canada through state-funded healthcare programs, including Medicaid, state prisons, and county health departments.
  ► Imported drugs would be those with the highest potential for cost savings to the state
  ► Suppliers must be in full compliance with all relevant Canadian laws and regulations and the Federal Food, Drug, and Cosmetic Act

► Vermont: S. 175
  ► Signed into law on May 16, 2018
  ► Creates an importation program to facilitate the purchase of costly drugs through authorized wholesalers by a designated state agency
  ► Imported drugs must be only those expected to generate substantial savings for Vermont consumers
  ► Importation proposal due to the federal government by July 1, 2019 for final approval
Key Takeaways and Predictions

► Bipartisan generic competition bills may be enacted by Congress by the end of 2019; need to be de-coupled from bills to strengthen ACA to secure Senate passage.
► Successful legal challenges to DTC price transparency and rebate final rule are possible.
► States will continue to enact transparency measures directed at PBMs and manufacturers; more states will take on an active purchaser role to curb drug spending.
► Current system of rebates will be transformed over time through public policy and private sector initiatives (e.g., POS rebates, transparency measures, etc.).
► Consumer impacts
  ► Medicare beneficiaries with high Part D drug costs could see the most substantive benefits in next few years from finalized rules by CMS and HHS-OIG. Medicaid beneficiaries will likely see little impact since their out-of-pocket costs are very low.
  ► Commercial customers (employers, individuals) will demand more plan designs customized to address specific needs (e.g., POS rebates, fixed copays, etc.).
  ► Additional customization of drug treatment therapies will continue to drive pricing pressures (e.g., gene therapy or patient-specific drugs).
Q&A

► Participant questions?

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Reps & Warranties in Healthcare Industry Transactions

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Issues to Consider in Preparing Representations and Warranties in Healthcare Industry Transactions

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I. THE BASICS

A. Representations and Warranties
   1. What should be covered?
   2. Who is making the representations and warranties?
   3. Definition of Knowledge
   4. Disclosure Schedule exceptions

B. Closely tied to Due Diligence

C. Types of Transactions
   1. Sale or affiliation transactions
   2. Joint ventures
   3. Service Agreements
   4. Licensing Agreements
   5. Financing Agreements (equity and debt)

D. The Consequences of Breach
   1. Right to terminate agreement
   2. Right to recover damages or losses
   3. Exposure to selling party

II. NON-HEALTHCARE REPRESENTATIONS WITH POTENTIAL HEALTHCARE IMPLICATIONS

A. Compliance with Law Representation

B. Litigation Representation

C. No Conflicts Representation (i.e. required consents and notices)

D. Intellectual Property Representations

E. Tax Representations
III. HEALTHCARE REPRESENTATIONS

Representations and warranties in healthcare transactions arise out of the regulatory status of the items and services offered by the parties to the transaction. Accordingly, it is very difficult to give a list of representations and warranties that will work for every transaction. To that end, rather than providing a list of sample provisions, we provide, below, a few areas for the parties to healthcare transactions to consider as they identify the risks attendant to the transaction and prepare representations and warranties to help allocate those risks.

A. Privacy and Security

1. What are the applicable regulatory schemes?
   - HIPAA
   - 42 C.F.R., Part 2
   - The EU GDPR
   - State laws

2. What types of information are collected?

3. How does information flow?

4. What types of consent have been obtained regarding the use of information?

5. What contractual arrangements have been made to assure privacy and security?
   - BAAs
   - Qualified Service Organization Agreements
   - GDPR Addenda
   - Other

6. Do the security measures in place allow the parties to meet their existing regulatory and contractual obligations regarding data security, as well as representations to consumers about security? Likewise, do the compliance infrastructure and information systems foster compliance with regulatory privacy and contractual data use obligations?

7. Have there been prior security breaches? What notifications were made?
B. Fraud and Abuse

1. What are the applicable laws?

   • Who are the relevant governmental payors, if any? Pay special attention to governmental managed care products (e.g., Medicaid managed care or Medicare Advantage), which are sometimes conceived of by businesspeople as “commercial business.”

   • Are state all-payor anti-kickback-type statutes and/or self-referral/disclosure laws in issue?

2. Does the sales and distribution strategy for the products and services involve value transfers to providers? Patients? Health plan members?

C. Tax-Exempt Organization Issues

1. Is the buyer or seller a tax-exempt organization?

2. Have all tax filings been made?

3. What policies are in place related to preserving tax-exempt status?

4. Have all filings been made related to charitable contribution solicitations and registrations?

5. Will the transaction result in a change of purpose/supporting organization filings?

6. Will the transaction generate unrelated business income?

D. Tax-Exempt Financing Issues

1. Is there tax-exempt financing?

2. Are there any compliance or reporting issues with the financing?

3. What notices and consents are needed?

4. Will the transaction result in “private use”?

5. Need to involve bond counsel and address repayment, refinancing, or amendment concerns.

E. Drug and Device Issues

1. What types of claims have been made regarding the product at issue?

2. What is the regulatory status of the products?
3. Have debarred individuals been involved in development/distribution of the product?

4. Who manufactures the product? If there is a contract manufacturer, what quality assurance process and procedures are in place?

5. Are there any certifications regarding the products that will need to be transferred as part of the transaction? Will the buyer be able to reference the predecessor safety and reporting history?

F. Call Center/Telemedicine Issues

1. Are services offered through a call center or online service?

2. If so, are professionals engaged in the practice of a licensed profession while doing so?

3. What are the credentials of the representatives speaking with consumers?

4. How is the program marketed?

5. Are drugs prescribed over the service? Controlled substances?

6. How have Telephone Consumer Protection Act risks been attended to?

G. Relationships with Healthcare Providers

1. Are healthcare providers involved in marketing a product or service to their patients?

2. What is the nature of any financial relationships with healthcare providers?

3. To the extent that a party is an “applicable manufacturer” under the Physician Payments Sunshine Act, are value transfers properly disclosed? (Same question under state aggregate-spend laws).

H. Corporate Practice of Medicine and Fee-Splitting

1. Does the transaction arguably involve lay control over the provision of healthcare services? How have these risks been addressed?

2. How do revenues for professional services flow?

3. What are the relevant prohibitions in the states is which the business operates or will operate?
I. Utilization Review

1. Does the service involve activity that arguably constitutes utilization review?

2. For whom are the services provided? Insured plans? Self-funded plans?

3. Are utilization review organization licensure schemes triggered?

4. Does the applicable regulatory scheme conceive of utilization review as constituting the practice of medicine?

J. Medicare and Medicaid Issues

1. Is there direct reimbursement from Medicare or Medicaid for the items or services in issue?

2. Is there reimbursement from Medicare or Medicaid managed care plans?

3. How do the parties check for exclusion? What lists are checked (OIG LEIE, GSA SAM, State Medicaid lists, etc.)?

4. How are government programs receivables handled to comply with the various reassignment prohibitions?

K. Licensure

1. Do the applicable entities and the relevant workforce members have required licenses?

2. Is assignment of a healthcare license to a new entity desired?
   - Note that acquirers are often treated as new applicants for licensure.
   - Note that the lead time for new applicants can be substantial and parties may need to address this in connection with collection of funds from services provided prior to closing (or explore the possibility of leasing back the operations to the seller).

3. Has jurisdictional nexus for licensure been appropriately considered, to the extent that a party transacts business across state lines?

4. Do any of the activities require insurance broker or agent licenses?

5. Has the selling entity made all regulatory report filings for the licenses it holds? Will the buyer have the information to complete any post-closing filings?

6. Are there any pending exams, investigations, or consent decrees?
7. Are there any bonds, letters of credit, or deposits supporting any licenses that need to be transferred to the buyer?

8. Are there any financial considerations related to statutory financial reporting or credit for reinsurance that need to be considered?

9. Is the buyer’s board familiar with the regulatory filing requirements? Will there be disclosure requirements for the board members as part of acquiring a regulatory business?

L. Provider Risk-Sharing

1. Is an entity not licensed as an insurer assuming risk for the payment of health benefits? If so consider the application of state law regarding the business of insurance and the Physician Incentive Plan rules of 42 C.F.R. Part 411.

2. How are provider risk-sharing arrangements structured? Do the agreements make it clear how to measure progress against forecasted losses and have clear settlement mechanisms?

3. Have licensure/registration obligations been properly attended to?

IV. REP AND WARRANTY INSURANCE

A. Available to address issues in larger transaction (generally over $50MM but beginning to be available for under $50MM as well)

B. May bridge gap on open topics and concerns

C. Not a substitute for due diligence or identifying any of the above issues

D. Underwriting process can require substantial management and legal time

E. Unlikely to be able to include known claims or licensing issues
The Future Is Now: 
Emerging Issues with Digital Therapeutics

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Overview

• Introductions
• What are Digital Therapeutics?
• FDA and FTC
• Intellectual Property
• Privacy and Security
• Provider Issues: Malpractice, Data Use and
  Ownership, Fraud and Abuse
• Future of Digital Therapeutics
• Q&A
Digital Therapeutics

• As defined by the Digital Therapeutics Alliance
  • Digital therapeutics (DTx) deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a broad spectrum of physical, mental, and behavioral conditions. Digital therapeutics form an independent category of evidence-based products within the broader digital health landscape, and are distinct from pure-play adherence, diagnostic, and telehealth products.

• DTx can be
  • just software
  • software used in conjunction with a medication
  • software that facilitates care delivery by humans in a non-traditional setting

What are digital therapeutics?

• Intervention based on software
  • software used to deliver evidence-based interventions

• Examples of device-like therapeutics
  • Pear Therapeutics—software-only substance abuse therapy
  • Proteus Digital Health-sensor-equipped pill with companion app
  • Akili Interactive Labs—video game-based pediatric ADHD treatment
  • Teva Pharmaceuticals—digital inhaler with built-in sensors and companion app
Digital Therapeutics

• Software with humans

How do digital therapeutics fit into the digital health ecosystem?
Digital Health Broadly (most not digital therapeutics)

- Health Apps
- Connected Devices / IoT
- Automation and Robotics
- Consumer apps and wearables
- Clinical Research
- Health IT / Services
- Telemedicine
- Medical Algorithms

The Role of Digital Health

- Use digital information with data science to improve outcomes and knowledge
- Cost
  - reduce inefficiencies inside a clinical setting
    - personalized medicine
    - process improvement
    - deliver care outside of institutions and buildings
The Role of Digital Health

• **Access**
  • ability to reach more people and break through cost and geographic barriers
  • provide supplemental services between visits

• **Consumerism**
  • provide a better consumer/member experience
  • use “commonplace consumer tools” (quoting CMS), because that is where consumers are
  • use data to reach and engage consumers in new ways
    • telemedicine
    • mHealth solutions

Differences?

• Not everything that is digital and encompasses health is a digital therapeutic
• Clinical Decision Support is not a digital therapeutic—it is more like a smart encyclopedia
• Wearables can feed digital therapeutics, but are not in of themselves therapeutic in a clinical sense
• Synchronous and a-synchronous communications between a doctor and a patient (texting, video conferencing), without the analytics software can supply, are not a digital therapeutic by themselves
• What areas of medicine are best positioned for digital therapeutics?

What areas of medicine are best positioned for digital therapeutics?

• chronic diseases/behavioral/mental
• shortage of providers compared to needed patient contact
• family members supplementing care
What are some of the evolving business models for digital therapeutics?

- Some digital therapeutics focus on value-based healthcare—Omada is an example
- Others bill PMPM/fee for service
- Others are prescribed—Pear Therapeutics
- Others are devices—Kaia
- Others help physicians manage risk and then share savings

• How does the FDA regulate digital therapeutics?
Regulatory Oversight

- FDA is interested in some digital therapeutics
- Other digital therapeutics are not “devices”, and are not within FDA’s jurisdiction (but may be within HIPAA)
- Most will have some aspect of FTC oversight

What are the regulatory challenges for digital therapeutics companies?

- FDA’s jurisdiction over “devices”
  - When should software be consider an FDA regulated “device”?
  - Are all digital therapeutics “devices”?
- FDA’s recent approach to regulating digital health
  - “encourage innovation”
- Recent Approval
  - Teva Pharmaceuticals
21st Century Cures Act

• Clarifies FDA jurisdiction over digital health products
  • excludes certain types of software from definition of "medical device"
  • excludes clinical-decision support software
  • Instantiates more software in healthcare that is not a "device" by requiring
    • certified EHRS to use open specification application programming interfaces—a kind of software application
    • prohibits information blocking

Digital Health Innovation Plan

• Implement 21st Century Cures Act
• Regulatory Oversight
  • Software Precertification (Pre-Cert) Pilot Program
“Clinical and Patient Decision Support Software” Draft Guidance

- Intended to “make clear what types of CDS would no longer be defined as a medical device, and thus would not be regulated by” FDA
- Provides that FDA will “continue to enforce oversight of software programs that are intended to process or analyze medical images, signals from in vitro diagnostic devices or patterns acquired from a processor like an electrocardiogram that use analytical functionalities to make treatment recommendations, as these remain medical devices under the Cures Act”

“Section 3060 Guidance”

- Outlines types of software FDA no longer considers medical devices (e.g. lifestyle or wellness apps)
- Proposes changes to FDA's earlier General Wellness products and Mobile Medical Applications and other guidance to “be consistent with the Cures Act and reflective of the agency’s new, more modern approach to digital health products”
“Section 3060 Guidance”

- Not “devices”
  - Software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition

“Software as Medical Device (SaMD): Clinical Evaluation”

- Goal: create common understanding of clinical evaluation and principles for demonstrating the safety, effectiveness and performance of SaMD
- Three key principles
  - valid clinical association
  - analytical validation
  - clinical validation
- If foregoing not established, manufacturer must revise the SaMD’s intended use consistent with available evidence, modify the target clinical association and/or make changes to the software
Who else is interested in digital therapeutics

- AMA--Coding for digital services
- CMS
  - Continuous Glucose Monitors
  - Virtual DPP
  - Asynchronous consultations in Medicare Advantage letter
- More rapid-cycle updates to CPT
- OIG--Data Integrity and Billing
- OCR--Privacy and Security

Final Thoughts on FDA and Digital Therapeutics...
• Direct to Consumer Advertising

Advertising Laws

• FDA
• Federal Trade Commission
  • FTC consumer protection law prohibits unfair or deceptive trade practices
    • applies to health claims
    • applies to privacy and security assertions
• Enforcement actions
  • Brain Game Apps
  • Acne Case
• State Laws
• What are some practical strategies for protecting intellectual property?

- Trade secrets vs. patents
  - *Alice Corp. v. CLS Bank International*
  - rapid technology turns
  - may be difficult to reverse engineer
- *Data as the new IP*
  - track data ownership; consolidate rights
  - Are health facts IP? *Association for Molecular Pathology v. Myriad Genetics, Inc.*
• What privacy and security issues do digital therapeutics companies need to address?

Privacy and Security

• Is digital therapeutic a HIPAA covered entity?
  • 45 CFR 160.103 is broader than Social Security Act (42 USC 1395x)
    • If covered entity, then no different than a physician’s office
• Is digital therapeutic a device?
  • FDA has no jurisdiction over privacy
  • FDA has jurisdiction over the data integrity aspect of security, but not the confidentiality aspect.
• Is the digital therapeutic a medication with a digital signal?
• Is digital therapeutic a business associate or vendor of a wellness program?
Privacy & Security cont’d

• Does digital therapeutic connect to some other org’s system?
  • Interoperability?
• Credentialing and authentication for required log-ins
  • If Otsuka Abilify, who is logging in to get signal the pill generates?
• Digital therapeutics are often 100% cloud based. What does that mean for your client’s risk concerns?

Complex Legal Landscape

• US: Patchwork of federal and state laws/regs and industry best practices
  • FTC Act – unfair or deceptive commercial practices
  • Potentially up for revision due to Facebook
• GLBA – banking and finance
• HIPAA – healthcare
• COPAA – collection of info from kids
• FCRA – consumer credit info
• CAN-SPAM – commercial e-mail
• State privacy laws – CA & MA
• State data breach notification laws
• Standards are constantly evolving
HIPAA

- Privacy Rule compliance
  - Digital signals and patient access to their own data
  - APIs and apps
- Security Rule compliance
  - New OCR FAQs: disclosers are not liable for the security errors of individuals using their own apps.
- Business associate issues
- Enforcement lag time
- Hacker focus on healthcare
- EHR issues

• Issues for physician/provider use or prescription of digital therapeutics?
Issues for physician/provider use/prescription of digital therapeutics

- Malpractice—standard of care
- Scope of Practice
- Privacy/Security
- Ownership of Data (IP issues)

Other Issues

- Fraud and Abuse
- Reimbursement