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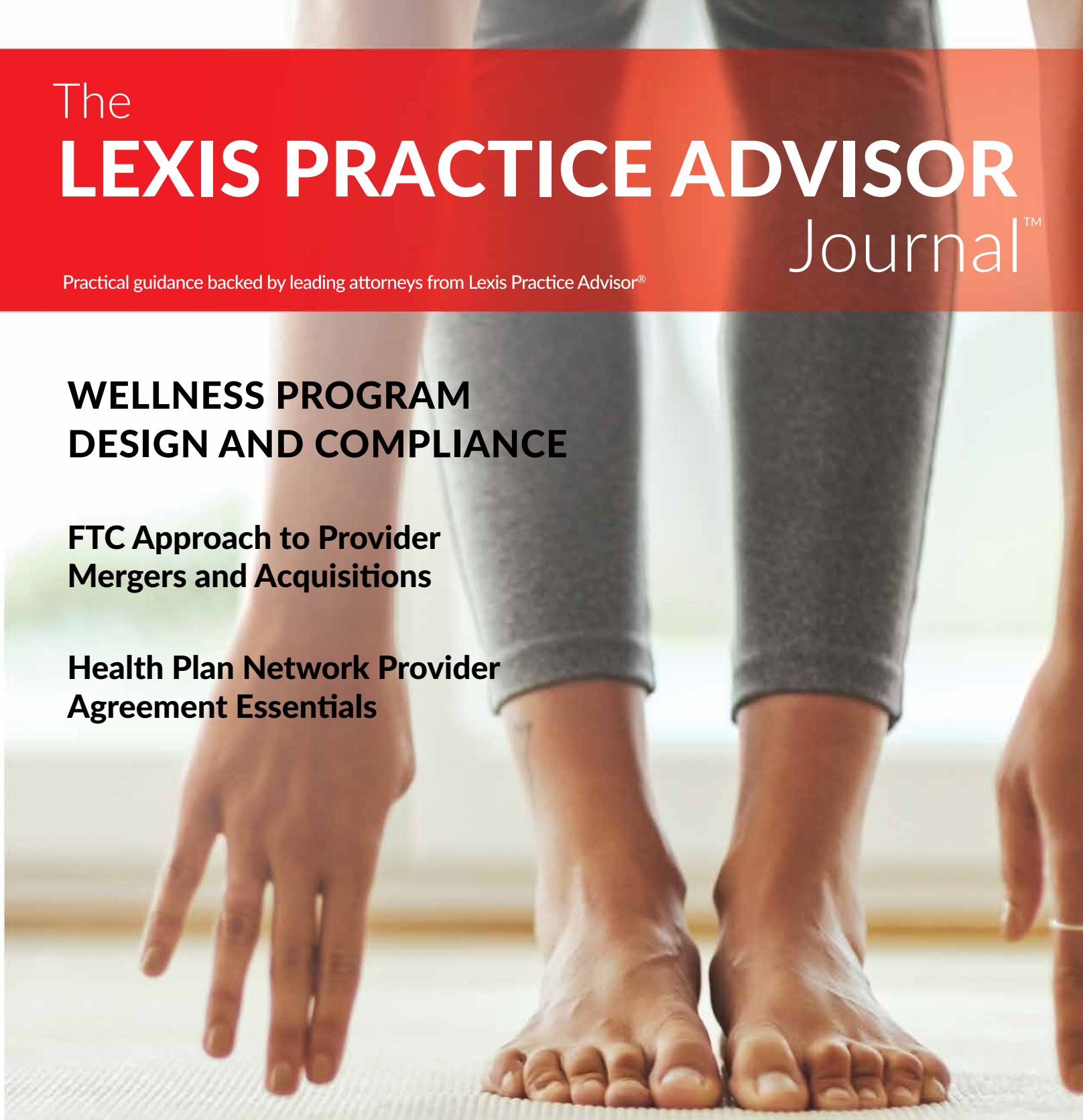

WELLNESS PROGRAM DESIGN AND COMPLIANCE

FTC Approach to Provider Mergers and Acquisitions

Health Plan Network Provider Agreement Essentials

SPECIAL EDITION 2019 - ISSUE 6, HEALTHCARE PRACTICE

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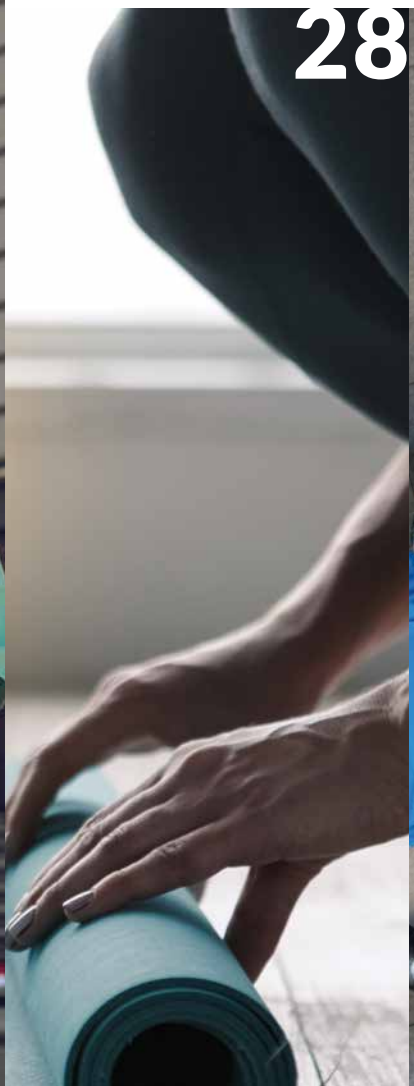

The
LEXIS PRACTICE ADVISOR Journal™

SPECIAL EDITION 2019 - Issue 6, Healthcare Practice

PRINTED BY — **Cenveo Publisher Services**
3575 Hempland Road
Lancaster, PA 17601

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The Lexis Practice Advisor Journal (Pub No. 02380; ISBN: 978-1-63284-895-6) is a complimentary publication published quarterly for Lexis Practice Advisor® subscribers by LexisNexis, 230 Park Avenue, 7th Floor, New York, NY 10169. **Email:** lexispracticeadvisorjournal@lexisnexis.com | **Website:** www.lexisnexis.com/lexispracticeadvisorjournal

Jason Brocks, Content Manager – Life Sciences and Healthcare

THIS SPECIAL EDITION OF THE LEXIS

Practice Advisor Journal focuses on Healthcare Practice. The articles highlight significant healthcare industry trends and related practical challenges faced by lawyers who represent healthcare providers, health insurers, employee benefit plans, and private equity firms, among others. The breadth of coverage underscores that healthcare-related issues arise in a range of legal practice areas and that they are subject to extensive federal and state regulatory scrutiny.

Wellness programs are popular among employers looking for ways to "bend the cost curve" associated with the provision of health benefits to their employees. The design and operation of wellness programs, however, raises HIPAA, ACA, and ADA compliance questions, among others. Attorneys from K&L Gates explain compliance issues, common pitfalls, and more in their informative article.

The idea of leveraging an association health plan (AHP) to provide less costly health benefits to employees, particularly for smaller companies, has received additional attention since the publication of a U.S. Department of Labor rule that expanded the types of entities that qualify as an association. While on its face the new rule appears to create potential opportunities, it also raises many questions for practitioners tasked with assisting their clients in the formation of an association health plan. Bryan Cave Leighton Paisner attorneys provide essential background information about the new rule in historical context and a guidance about forming an AHP.

The purchase of medical practices by hospitals and health systems, private equity funds, and insurers has increased over the past few years. Healthcare M&A deals including medical practice purchases are fraught with legal and compliance risks arising out of stringent healthcare fraud and abuse, licensing, and antitrust laws, among others. An article contributed by Seyfarth Shaw guides you through the unique legal considerations inherent in acquisitions of physician medical practices.

As the popularity of ambulatory surgery centers (ASCs) has increased as an alternative to hospital-based surgery, so has the real estate activity related to them. In many cases, the cost of owning and operating an ASC is prohibitive. As a result, hospitals and health systems or other well-capitalized entities fund ASC construction, assume ownership, and rent space to doctors and medical groups. As with other transactions in the healthcare industry, lawyers representing ASC owners and tenants must understand the regulatory environment in which ASCs operate to appropriately advise their clients about the risks associated with an ASC lease. Attorneys from McGuireWoods explain why these arrangements are so different from traditional office space leases.

The U.S. Department of Justice (DOJ) Antitrust Division has been front-and-center in many recent health insurance merger deals. As mergers involving health insurers become increasingly common, it is important for attorneys representing health insurers to understand the nature of the concerns expressed by DOJ and how to mitigate the regulatory risks posed by health insurance mergers. Crowell & Moring attorneys discuss the DOJ's approach to analyzing mergers between health insurers, point out red flags, and provide guidance on how to mitigate enforcement risks.

Finally, health insurers take care of their members' healthcare needs through networks of doctors, dentists, and other healthcare providers who provide treatment. This issue includes practical guidance for attorneys tasked with negotiating and drafting healthcare provider agreements between insurers and their network providers.

We hope you enjoy this Healthcare Practice issue of The Lexis Practice Advisor Journal and that you will apply the tools and guidance within it and at Lexis Practice Advisor online to your next healthcare deal.

Our mission

The Lexis Practice Advisor Journal™ is designed to help attorneys start on point. This supplement to our online practical guidance resource, Lexis Practice Advisor®, brings you a sophisticated collection of practice insights, trends, and forward-thinking articles. Grounded in the real-world experience of our 850+ seasoned attorney authors, the Lexis Practice Advisor Journal offers fresh, contemporary perspectives and compelling insights on matters impacting your practice.

EEOC LEAVES WORKPLACE WELLNESS PROGRAMS IN LIMBO

EFFECTIVE JANUARY 1, 2019, REGULATIONS ISSUED by the Equal Employment Opportunity Commission (EEOC) concerning incentive-based workplace wellness programs are rescinded, leaving employers without guidance until at least June.

By way of background, in May 2016, the EEOC had finalized regulations explaining how employers could provide financial and other incentives to employees for answering disability-related questions and taking medical exams or having their spouses provide information about current or past health status. The EEOC designed the regulations to promote workplace wellness without running afoul of the Americans with Disabilities Act of 1990 (ADA) (Pub. L. No. 101-336, 104 Stat. 327 (July 26, 1990)) or the Genetic Information Nondiscrimination Act (GINA) (Pub. L. No. 110-233, 122 Stat. 881 (May 21, 2008)).

Under the final ADA regulation, employers could offer wellness programs asking questions about health or including medical examinations in exchange for incentives of up to 30% of the total cost of the employee's "self-only" health insurance plan. The final GINA regulation applied the same maximum incentive for information provided by employees' spouses. The EEOC also claimed that the rules complied with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. No. 104-191, 100 Stat. 2548 (Aug. 21, 1996)).

In October 2016, the American Association of Retired Persons (AARP) brought suit on behalf of its members, arguing that the regulations (81 Fed. Reg. 31,126 and 81 Fed. Reg. 31,143) violated the ADA and the GINA provisions requiring that the disclosure of health information to an employer be "voluntary," and that employees who would not otherwise choose to do so would be forced to disclose information to take advantage of the health coverage costs offered by the wellness programs.

According to the regulations, "in order for the participation in an employee health program to be voluntary, a covered entity may not require employees to participate, deny access to health coverage for nonparticipation, generally limit coverage under its health plans, take any other adverse action, or retaliate, interfere with, coerce, intimidate, or threaten an employee who does not participate or fails to achieve certain health outcomes, and must provide a notice clearly explaining what medical information will be obtained, how it will be used, who will receive it, and the restrictions on disclosure."

In August 2017, U.S. District Judge John Bates of the U.S. District Court for the District of Columbia ruled that the EEOC had failed to justify the 30% figure and ordered it to reconsider it "in a timely manner." AARP v. United States EEOC, 267 F. Supp. 3d 14 (D.D.C. 2017). However, the court found that vacating the regulations altogether would cause "widespread disruption and confusion."

The AARP subsequently moved for vacatur of the regulations and Judge Bates granted the motion in December 2017, setting an effective date of January 1, 2019. He directed the EEOC to issue a notice of proposed rulemaking by August 2018. AARP v. United States EEOC, 292 F. Supp. 3d 238 (D.D.C. 2017).

In January 2018, Judge Bates granted a motion by the EEOC to partially vacate the December 2017 order by removing the August 2018 rulemaking deadline. AARP v. United States EEOC, 2018 U.S. Dist. LEXIS 27317 (D.D.C. 2018).

In October 2018, the EEOC indicated that new rules would not be promulgated until June 2019, at the earliest. On December 20, 2018, the agency published notices of its intent to rescind the ADA and GINA regulations as of January 1, 2019.

The Meaning of "Voluntary"

The ADA and the GINA generally prohibit employers from asking employees about their and their families' health unless the questions are "voluntary." However, the laws don't define the word "voluntary," which had left employers in a difficult situation if they wanted to implement wellness programs. The Affordable Care Act of 2010 (ACA) (Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010)) amended HIPAA to allow employers to raise or lower their employees' health insurance premiums by 30% if they participated in wellness programs, but it wasn't until the EEOC finalized its regulations in 2016 that employers had some certainty about what they were permitted to do under the ADA and GINA.

Employers offer wellness programs to encourage workers to invest in their health and to save on the cost of insurance, among other reasons. However, with the incentive provisions of the rules vacated, employers are at some risk of EEOC action or private suits challenging their existing programs as coercive. These types of suits were filed in the years prior to the 2016 rules.

Takeaways for Employers in the Interim

Now that the EEOC has offered an opinion as to what it perceives to be voluntary, employers are in a better position to make judgment calls when assessing their current incentive programs. As long as employers' programs are in line with the 2016 rules, experts say it is unlikely that the EEOC will sue them for coercive policies. It helps that Judge Bates left untouched other sections of the law that help employers ensure that they are not forcing workers to take part. These include provisions about confidentiality requirements, the methods employers use to communicate with workers, and how programs are designed to make employees healthier. Employers can look to the vacated guidelines as a framework, and now must carefully take into consideration what is "voluntary" under the ADA.

RESEARCH PATH: *Labor & Employment > Workplace Safety and Health > Articles*

FEDERAL JUDGE DEEMS DOL HEALTHCARE RULE UNLAWFUL UNDER ERISA, ACA

ON MARCH 28, 2019, A FEDERAL JUDGE IN WASHINGTON, D.C. rejected a significant provision in a Trump administration regulation on association health plans, "Definition of 'Employer' Under Section 3(5) of ERISA—Association Health Plans" (Final Rule) (29 C.F.R. 2510). In New York v. United States Dep't of Labor, 2019 U.S. Dist. LEXIS 52725 (March 28, 2019).

U.S. District Judge John Bates found that language in the Department of Labor's (DOL) regulation permitting small businesses and self-employed individuals to band together for the purpose of buying health insurance on the large-group market functions as an unlawful and clear "end-run" around the Affordable Care Act (ACA) (Pub. L. No. 111-148, 124 Stat. 119 (2010). Judge Bates also found that the rule misrepresents the meaning of the term "employer" as it is used in the Employee Retirement Income Security Act (ERISA) (29 U.S.C.S. § 1001, *et seq.*), and that it constitutes an attempt to unlawfully expand the term's meaning in violation of the Administrative Procedure Act (5 U.S.C.S. § 706).

The ruling came in a lawsuit against the DOL brought in July by the attorneys general of California, Delaware, Kentucky, Maryland, Massachusetts, New Jersey, New York, Oregon, Pennsylvania, Virginia, Washington, and Washington, D.C., alleging that the rule violates the "text, structure and purpose" of the ACA and is premised on a misreading of ERISA. Judge Bates ruled that the attempted expansion of the term "employer" disregards the ACA's "careful statutory scheme distinguishing rules that apply to individuals, small employers and large employers." By allowing unrelated small employers (or self-employed individuals) to form associations to offer health coverage to their members, they could avoid certain ACA requirements contrary to Congressional intent.

"For decades," the judge explained, DOL has only permitted "bona fide associations" of employers "with close economic and representational ties to their employer members" to be considered "employers" under ERISA, and therefore empowered to purchase large-group insurance on the market for their employees. The 2018 Final Rule flouts this requirement, he said. The purpose, he found, is to permit small businesses and some individuals "to avoid the healthcare market requirements imposed by the ACA," which the law does not allow. In fact, Judge Bates noted, the President himself directed that the DOL design the Final Rule to accomplish this very result and acknowledged that its purpose was to avoid the stringent rules of the ACA, as evidenced by the language in his executive order directing the DOL to promulgate what became the Final Rule. 82 Fed. Reg. 48,385 (Oct. 12, 2017).

The judge remanded the rule to the DOL to permit the agency to try to address the possible severability of the invalidated portion.

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Articles*

DOJ ASKS FIFTH CIRCUIT TO AFFIRM TEXAS COURT RULING INVALIDATING AFFORDABLE CARE ACT

AS BRIEFING GOT UNDERWAY IN THE U.S. COURT OF Appeals for the Fifth Circuit in the appeal from a Texas judge's decision striking down the Patient Protection and Affordable Care Act (ACA), the U.S. Department of Justice on March 25 notified the court's clerk of the government's opinion that the ruling should be upheld and its intent to file a brief to that effect. Texas v. United States, No. 19-10011 (5th Cir.).

"The Department of Justice has determined that the district court's judgment should be affirmed. Because the United States is not urging that any portion of the district court's judgment be reversed, the government intends to file a brief on the appellees' schedule," the letter stated.

U.S. Judge Reed O'Connor of the Northern District of Texas ruled Dec. 14, 2018 that as a result of a provision contained in the Tax Cuts and Jobs Act of 2017 (TCJA) (115 P.L. 97) effectively reducing to zero the ACA's individual mandate tax penalty as of Jan. 1, 2019, the individual mandate is no longer a valid exercise of Congress' taxing power. Further, the judge said, the individual mandate is inseverable from the remainder of the ACA, rendering the entire statute invalid. Texas v. United States, 2018 U.S. Dist. LEXIS 211547 (Dec. 14, 2018).

The ruling came in a suit filed by a group of Republican state attorneys general challenging the constitutionality of the ACA. Democratic attorneys general from 16 states and the District of Columbia intervened and ultimately appealed to the Fifth Circuit.

In their opening brief, the appellant states argued that the plaintiffs below lack standing, that the individual mandate is constitutional, and, alternatively, that the individual mandate is severable from the remainder of the ACA.

In a separate brief, the House of Representatives, as intervenor, echoed the arguments advanced by the appellant states.

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Articles*

HHS AGENCIES ISSUE PROPOSED RULES ON ELECTRONIC HEALTH INFORMATION ACCESS, EXCHANGE

IN A COORDINATED EFFORT, TWO AGENCIES WITHIN THE Department of Health and Human Services (HHS) on February 11 proposed rules to enhance the interoperability of electronic health information (EHI) and improve access to, and the quality of, information needed by consumers to make informed healthcare decisions.

The proposed rules are aimed at clarifying and implementing provisions in the 21st Century Cures Act of 2016 (Pub. L. No. 114-225, 130 Stat. 1033 (Dec. 13, 2010)) related to interoperability, information blocking, and certification of health information technology developers.

The first proposed rule, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program", https://www.healthit.gov/sites/default/files/nprm/ONCCuresActNPRM.pdf, issued by the Office of the National Coordinator for Health Information Technology (ONC), would implement "certain provisions of the Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program, the voluntary certification of health IT for use by pediatric healthcare providers, and reasonable and necessary activities that do not constitute information blocking."

In addition, the proposed rule would modify the ONC Health IT Certification Program in order to "advance interoperability, enhance health IT certification, and reduce burden and costs."

The proposed rule has been published at 84 Fed. Reg. 7,424.

The second proposed rule, issued by the Centers for Medicare & Medicaid Services (CMS), is entitled "Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers." It was published in the Federal Register on March 4 at 84 Fed. Reg. 7,610 https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02200.pdf.

CMS said in a summary that it is "committed to solving the issue of interoperability and achieving complete access to health information for patients in the United States healthcare system" and is "taking an active approach to move participants in the healthcare market toward interoperability and the secure and timely exchange of health information." The regulation targets Medicare and Medicaid programs, the Children's Health Insurance Program, and issuers of qualified health plans.

The proposed rule is aimed at making patient data "more useful and transferable through open, secure, standardized, and machine-readable formats while reducing restrictive burdens on healthcare providers."

Comments on the proposed CMS rule can be filed electronically, by regular mail, or by overnight delivery, and must be received by 5 p.m. on May 3.

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Articles*

PENNSYLVANIA FEDERAL JUDGE ENJOINS ENFORCEMENT OF ACA CONTRACEPTIVE COVERAGE RULES

A FEDERAL JUDGE IN PHILADELPHIA HAS ISSUED A nationwide injunction against enforcement of regulations that would expand the categories of employers who can refuse to provide contraceptive coverage to employees on religious or moral grounds Commonwealth of Pennsylvania v. Trump, 2019 U.S. Dist. LEXIS 6161 (E.D. Pa. Jan. 14, 2019). The ruling by U.S. Judge Wendy Beetlestone of the Eastern District of Pennsylvania blocks enforcement of two regulations that would have taken effect on Jan. 14. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018) and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 FR 57,592. While religious organizations were already exempted from the obligation to provide coverage, the new regulations would apply to non-religious employers, including publicly-traded companies.

The regulations, issued by the U.S. Departments of Health and Human Services (HHS), Labor and the Treasury, and finalized in November 2018, stem from an executive order issued in May 2017 by President Donald J. Trump directing federal agencies to consider issuing amended regulations to address "conscience-based objections" to a provision in the Patient Protection and Affordable Care Act (ACA) (Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010)) requiring employers to provide no-cost birth control coverage to employees. "Promoting Free Speech and Religious Liberty," Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017).

The Commonwealth of Pennsylvania and the State of New Jersey challenged the rules and moved for preliminary injunctive relief.

Granting the motion, Judge Beetlestone said that the regulations exceed the scope of the authority granted to the three agencies under the ACA. "The fact that there is no religious or moral exemption in the explicit text of the statute, while there is an exemption for grandfathered health plans, militates against finding that Congress authorized the Agencies to create any additional exemptions," the judge held. "Indeed, that interpretation is supported by the legislative history, given that, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to that contained in the Final Rules."

The judge also rejected the government's contention that the exemptions are permissible under the Religious Freedom Restoration Act (42 U.S.C.S. § 2000bb), saying that the statute "explicitly provides a private cause of action" and "commits to the courts the task of determining whether generally applicable laws violate a person's religious exercise."

Judge Beetlestone found further that Pennsylvania and New Jersey have demonstrated the requisite likelihood of irreparable harm in the absence of injunctive relief. Specifically, she said, the states have produced evidence that they will have to provide contraceptive services via state-funded programs to women left without coverage. In addition, the states have shown that enforcement of the regulations will cause harm to their interest in protecting the safety and well-being of their citizens, including women who might face unwanted pregnancies as a result of the regulations. "The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible," the judge said.

Finally, the judge said, a nationwide injunction is the most effective way to provide complete relief to the two states. "An injunction limited to the Third Circuit, for example, would fail to account for the thousands of Pennsylvania and New Jersey citizens that commute to neighboring or nearby states outside the Third Circuit for work," the judge said. "Similarly, an injunction covering the surrounding states would not account for the fact that the States draw out-of-state students from across the nation."

The ruling came just a day after a federal judge in Oakland, California, issued a similar order covering 13 plaintiff states (California, Connecticut, Delaware, Hawaii, Illinois, Maryland, Minnesota, New York, North Carolina, Rhode Island, Vermont, Virginia, and Washington) and the District of Columbia. California v. HHS, 2019 U.S. Dist. LEXIS 6554 (N.D. Calif. Jan. 13, 2019).

Both decisions are expected to be appealed, regardless of whether the preliminary injunctions are made permanent, with the U.S. Supreme Court widely predicted as the ultimate destination for the issue.

RESEARCH PATH: *Labor & Employment > Workplace Safety and Health > Articles*

William B. Eck SEYFARTH SHAW LLP

Physician Practice Acquisitions: Avoiding Legal Pitfalls

This article focuses on the special merger and acquisition considerations applicable to physician practice acquisitions. The past couple of years have seen a resurgence in the acquisition of physician practices, both by hospitals and by private equity firms. Hospitals and health systems are increasingly looking for clinical integration. Private equity firms see the advantages that large, integrated groups have to offer. Independent physician groups are faced with significant challenges.

THESE INCLUDE NOT ONLY CONTINUED REIMBURSEMENT rate pressure, but also reimbursement methodology challenges, such as the Medicare Access and CHIP Reauthorization Act of 2015 (popularly known as MACRA), that fundamentally alter the manner in which physicians are paid and demand implementation of sophisticated and expensive technology that small groups can ill afford.

Recent physician group acquisitions include the 2017 acquisition by Indiana University Health of Premier Healthcare, one of Indiana's largest independent physician groups, which employs 40 primary care and specialty doctors. Also in 2017, MEDNAX, a national health solutions partner represented in all 50 states, acquired both Radiology Alliance, the largest private practice radiology group in Tennessee with 64 physicians and, in a separate transaction, Synergy Radiology Associates, P.A., a Houston-area radiology group made up of more than 90 physicians.

Acquiring a physician group carries special challenges in view of the heavy regulation of the healthcare provider industry. Once it is decided to acquire a physician practice, among the questions the acquirer and its counsel must consider are the optimal structuring approaches and how to avoid the legal pitfalls that are particular to this sort of transaction.

Structure of the Transaction

In general, the threshold consideration in a physician practice acquisition is the structure of the transaction. Typically, the acquisition may be an asset acquisition, a stock acquisition, or a merger. Certain states prohibit persons or entities other than physicians from owning physician practices. In those states that prohibit the corporate practice of medicine, the transaction may take more complex forms, such as asset purchases followed by long-term management relationships. In some states, hospitals may own practices, but private equity firms may not. In others, even hospitals may not own physician practices. In such states, it is common for the transaction to take the form of a purchase of assets other than goodwill, coupled with a practice management agreement. Counsel should review the specific form of transaction from the perspective of the state's practice-of-medicine law and policy regarding the ownership and management of physician practices by non-physicians.

From the standpoint of the buyer, an asset acquisition is the most advantageous of the alternatives. First, except in limited circumstances, it allows the buyer to obtain the practice free and clear of prior liabilities and contingencies. Second, it allows the buyer a step up in the tax basis of the purchased assets (the parties to a stock purchase may also elect to have the transaction treated as an asset purchase for federal income tax purposes). Conversely, a stock purchase or merger transaction will typically be a more tax-efficient alternative for the seller.

Stock purchases and mergers also have the advantage that they usually involve few to no third-party consents. An asset purchase, on the other hand, in a physician practice context usually will require consents to the assignment of leases and agreements. Importantly, an asset purchase will require either new Medicare, Medicaid, and other governmental and commercial payer agreements or assignments of existing payer agreements.

Although new payer agreements can be cumbersome to obtain, they provide avoidance of liability for prior Medicare, Medicaid, and commercial insurance overpayments that could otherwise become an issue under the target's payer agreements. This is often an important reason for the buyer to seek an asset purchase structure, unless the seller has particularly favorable commercial insurance payer agreements. With an asset purchase structure, the buyer can decline to accept assignment of provider agreements, and instead, apply and enroll as a new provider. In general, a new subsidiary should be formed as the buyer; otherwise, the buyer's existing governmental and commercial insurance payer contracts may become applicable to the post-closing practice as a new location of the buyer. Similarly, in an asset purchase, the buyer generally takes the practice free from liabilities and contingencies for alleged pre-closing malpractice events. In this manner, the buyer may begin afresh, without exposure to potential Medicare, Medicaid, private overpayment claims, or malpractice contingencies.

Due Diligence

Anti-kickback Statutes

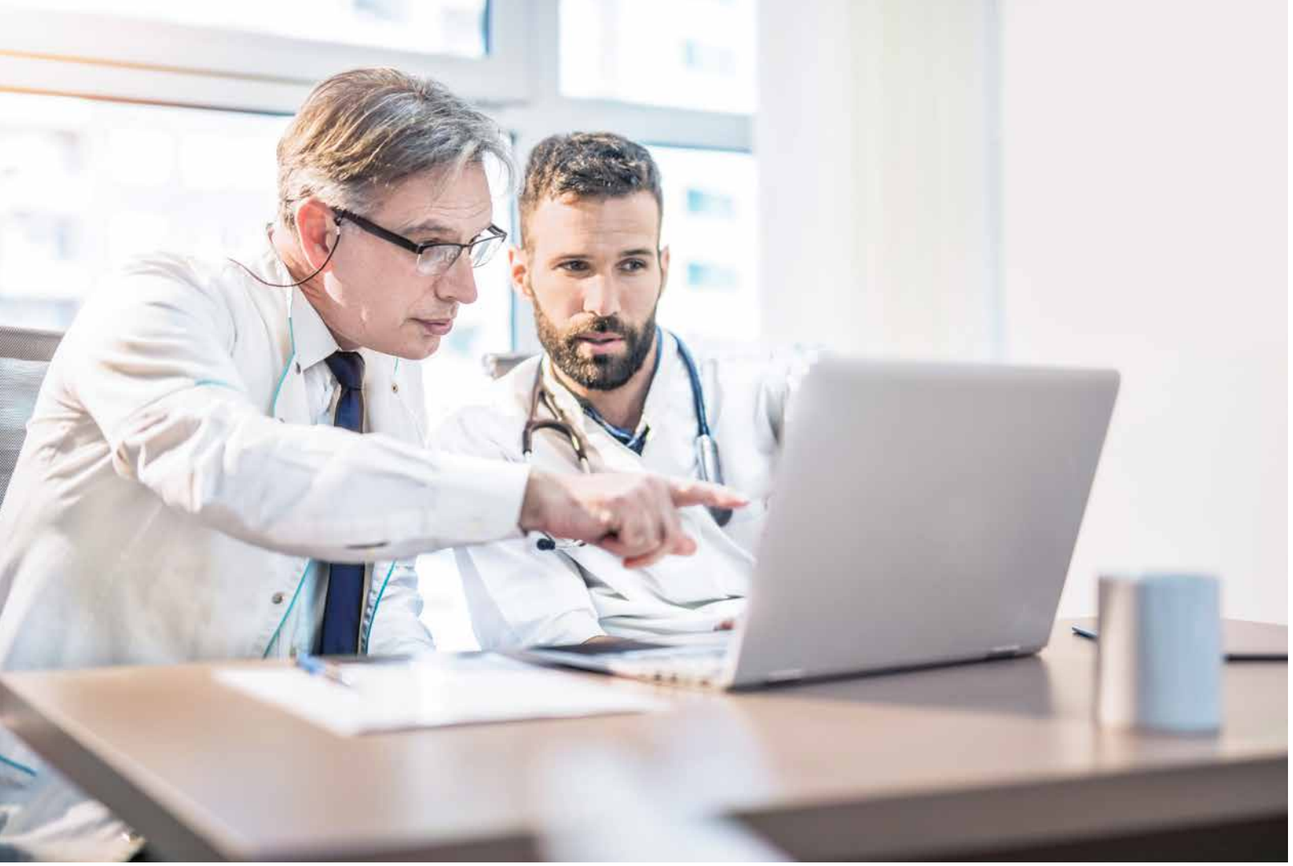
In addition to the matters typically addressed in due diligence for any merger and acquisition transaction, in a physician practice acquisition, attorneys performing due diligence must address certain health regulation matters. These include the federal healthcare anti-kickback statute (AKS)[1] and its state counterparts.[2] The AKS prohibits direct or indirect remuneration in return for or to induce referrals for items or services for which federal healthcare program (e.g., Medicare or Medicaid) payment may be made. State laws are similar and usually apply to all payers, not only federal healthcare program payers. The due diligence required involves review of all of the practice's contracts with referral sources and with entities to which the physicians refer. Likewise, counsel should review each physician's contracts with referral sources and with recipients of referrals, and other key contracts of the practice and its physicians. The critical review consideration is whether it appears that inappropriate remuneration in return for or to induce referrals is involved in the agreement.

Stark Laws

Counsel should review compliance with the Stark law[3] and its state counterparts.[4] With certain limited exceptions, the Stark law prohibits physicians from making referrals for specified designated health services, where the physician or an immediate family member of the physician has a compensation relationship or investment interest in the provider or supplier of the designated health service. "Designated health services" as defined in the Stark law are:

a. Clinical lab services
b. Physical therapy
c. Occupational therapy
d. Radiology, including MRI, CT, and ultrasound
e. Radiation therapy
f. Durable medical equipment and supplies
g. Parenteral and enteral nutrients, equipment, and supplies
h. Prosthetics, orthotics, and prosthetic devices and supplies
i. Home health services
j. Outpatient prescription drugs
k. Inpatient and outpatient hospital services
l. Outpatient speech-language pathology services

1. 42 U.S.C.S. § 1320a-7(b). 2. *See e.g.*, N.Y. Soc. Serv. Law § 366-d; Cal. Bus. & Prof. Code § 650. 3. 42 U.S.C.S. § 1395nn. 4. *See e.g.*, N.Y. Pub. Health Law § 238-a; Cal. Bus. & Prof. Code § 650 et seq.



Counsel performing due diligence should review physician relationships with all non-practice providers and suppliers of designated health services, including hospitals and other practices, for compliance with the Stark law. Also, if the group provides designated health services, such as clinical lab or imaging services, or certain other in-office ancillary designated health services, counsel should review compliance with the Stark law exception for in-group ancillary services.[5]

Compliance Policies and Procedures

Counsel should review any compliance program, compliance policies and procedures, and compliance log of the physician practice. The compliance policies and procedures will indicate how robust the group's effort is to comply with applicable laws and regulations, as well as the extent to which it follows the guidance of the U.S. Department of Health and Human Services' (HHS) Office of the Inspector General.[6] The compliance log is one indicator of the level of the group's overall compliance with laws and regulations and whether there are material issues that will need to be addressed. These issues may relate not only to healthcare compliance but also to compliance with employment or other laws and regulations.

Coding and Billing Practices

The buyer should consider whether to perform a coding and billing audit, if only on a relatively small sample of claims. Even if the transaction is structured as an asset purchase, to the extent that the practice's financial results were achieved based on aggressive coding and billing practices, this could affect the valuation of the practice.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) and State Privacy Law Compliance

Counsel should review the target practice's compliance with HIPAA and parallel state privacy laws. The buyer will want to ensure that an appropriate notice of privacy practices is in place and followed. The buyer will also want to ensure that up-to-date and appropriate business associate agreements are in place with billing companies and other business associates. Finally, the buyer will want to confirm that appropriate information security systems are in place.

5. 42 U.S.C.S. § 1395nn(b)(2). 6. *See* OIG Compliance Program Guidance for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434 (Oct. 5, 2000).

Related Content

For information on change of ownership considerations for healthcare providers that are reimbursed for services under Medicare, see

> **MEDICARE AND MEDICAID CHANGE OF OWNERSHIP CONSIDERATIONS IN HEALTHCARE INDUSTRY M&A**

RESEARCH PATH: *Corporate and M&A > M&A by Industry > Healthcare M&A > Practice Notes*

For an analysis of the benefits and drawbacks of asset acquisitions, private stock acquisitions, and mergers, see

> **ASSET PURCHASE, STOCK PURCHASE, AND MERGER STRUCTURES: BENEFITS AND DRAWBACKS**

RESEARCH PATH: *Corporate and M&A > Structuring and Planning a Deal > Fundamentals of Structuring and Planning > Practice Notes*

For a discussion on key considerations when drafting and negotiating a non-compete agreement, see

> **NON-COMPETITION, NON-SOLICITATION, NON-DISPARAGEMENT, AND CONFIDENTIALITY AGREEMENTS IN M&A DEALS**

RESEARCH PATH: *Corporate and M&A > Ancillary Agreements > Non-Competition and Confidentiality Agreements > Practice Notes*

Licensing Regulations

Counsel should confirm the physicians' licensure status. Also, depending on the type of physician practice, compliance with other applicable licensing laws and regulations should be reviewed. It may be the case, depending on the specialty of the practice, that it will hold other licenses, such as equipment licenses, the status of which should be confirmed. For example, a radiology practice may have imaging equipment required to be licensed. Other equipment sometimes in physician practices and required to be licensed includes nuclear medicine equipment and accelerators. As part of due diligence, it is advisable to assure that these licenses are in place, up to date, and no violations are outstanding. Assignments of these licenses (other than physician licenses to practice medicine) may also be necessary depending on the structure of the transaction and the licensing laws of the relevant state.

Valuing the Practice and Physician Compensation

Where the purchaser will employ the physician and be the recipient of referrals from the physician subsequent to the purchase, such as a hospital or health system purchaser, it is important that the transaction be within the Stark law exception for isolated transactions.[7] Most significantly, this exception requires that consideration (1) be fair market value, (2) not be determined in a manner that takes into account the volume or value of referrals, and (3) be commercially reasonable even if no referrals were made.[8] The employment compensation subsequent to the purchase must meet the same requirements.

In recent, high-profile cases, including, for example, *United States ex rel. Schaengold v. Memorial Health, Inc.*, the purchase price of physician practices and compensation of physicians were claimed by the government to violate the Stark law where the purchaser and subsequent employer was a hospital or health system.[9] In *Schaengold*, the government claimed that the health system violated the False Claims Act due to underlying Stark law violations. The court denied the health system's motion to dismiss, holding that there was a plausible claim. The health system settled the case by payment of $9.9 million to the government.

Similarly, in *United States ex rel. Drakeford v. Tuomey*, the compensation of surgeons as part-time employees was ruled to violate the Stark law because it included productivity and incentive bonuses that, although based on professional services, would be higher with greater referrals.[10] Therefore, the compensation was determined to "take account of" referrals for Stark law purposes. In *Tuomey*, there was a $275 million verdict and judgment against the health system, and the case ultimately settled for $72.4 million.

Stark law or AKS violations are less of a concern where the purchaser is a firm that will not be a recipient of referrals from the physicians subsequent to the closing of the purchase. However, in the case of a hospital or health system purchaser and employer, the hospital or a hospital within the health system typically will be the recipient of referrals after completion of the purchase. Under the Stark law, the purchase price and compensation of the physicians may not take account of or compensate these referrals.

Similarly, as noted, the AKS prohibits any remuneration, direct or indirect, overt or covert, in exchange for or to induce, referrals for which Medicare, Medicaid, or other federal healthcare program payment may be made. The AKS applies to the offer or receipt of, as well as to the solicitation or payment

7. *See* 42 U.S.C.S. § 1395nn(e)(6). 8. *Id.* 9. United States *ex rel.* Schaengold v. Mem'l Health, Inc., 2014 U.S. Dist. LEXIS 169555 (S.D. Ga. December 18, 2014). 10. United States *ex rel.* Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015).

As with other acquisition transactions, as an initial matter, counsel needs to determine whether a pre-merger notification filing under the Hart-Scott-Rodino Act (HSR) is necessary. For 2019, the threshold for HSR filings is $90 million; therefore HSR filing requirements apply only to large physician practice acquisition transactions.

for, referrals. Violations of the AKS are felonies.[11] Similar to the Stark law, the AKS may be implicated to the extent that the purchase price is based on present or anticipated referrals or where the physician practice will refer to the purchaser or affiliate of the purchaser after completion of the purchase.

The AKS contains a safe harbor that may protect payments of compensation for services to bona fide physician employees subsequent to the purchase. Here, the definition of employees is for federal income tax purposes.[12] However, as illustrated by *Schaengold*, compliance with the AKS does not constitute compliance with the Stark law, and the Stark law may be violated even where the AKS is complied with. Because of the potential for scrutiny of physician compensation under the Stark law, and scrutiny of the purchase price under the AKS and Stark law, if practice physicians will refer patients to the buyer or an affiliate of the buyer after completion of the purchase, it is advisable to consider an independent third-party valuation of the fair market value and commercial reasonableness of the compensation of physicians and purchase price of the practice. A valuation by an independent expert consultant will minimize risk that physician compensation or the purchase price would be determined to run afoul of the Stark law or the AKS.

Although the AKS contains a regulatory safe harbor for sales of practices, it applies only to sales from one practitioner to another.[13] The fact that a transaction is not within a safe harbor does not mean it violates the AKS. However, the facts and circumstances of the arrangement are subject to scrutiny by the HHS Office of Inspector General or, in the context of a False Claims Act case, the Department of Justice. Consequently, it is critical that the consideration in the purchase not be based on or take account of present or anticipated referrals.

Antitrust Issues

As with other acquisition transactions, as an initial matter, counsel needs to determine whether a pre-merger notification filing under the Hart-Scott-Rodino Act (HSR) is necessary. For 2019, the threshold for HSR filings is $90 million; therefore HSR filing requirements apply only to large physician practice acquisition transactions.

However, it is important to keep in mind that, while most physician practice acquisitions will not require pre-merger filing with the Federal Trade Commission (FTC), there is a potential for larger transactions to trigger antitrust scrutiny under the Clayton Act. There is even the potential for smaller acquisitions to trigger scrutiny in rural markets or in highly specialized practice areas. This occurred in at least one case, in Idaho, with a practice comprised of 34 physicians.[14]

On December 15, 2017, the U.S. District Court for the District of North Dakota granted the FTC's and the North Dakota attorney general's motion for a preliminary injunction, halting the proposed acquisition of Mid Dakota Clinic, P.C. (Mid Dakota) by Sanford Health (Sanford), until an administrative trial before the FTC is complete.[15] Sanford employs 160 physicians and 100 non-physician providers in the Bismarck-Mandan, North Dakota area. Sanford also sells health insurance. Mid Dakota is a multi-specialty physician practice employing 60 physicians and 19 advanced practice practitioners. Mid Dakota also operates six clinics, a Center for Women, and an ambulatory surgical center primarily in Bismarck, North Dakota.

The court found the transaction presumptively illegal, further concentrating an already concentrated market. The court rejected Mid Dakota's and Sanford's efficiency arguments, with the view that efficiencies almost never justify a merger to a monopoly or near monopoly. The case is presently under appeal, and the FTC administrative trial is pending the outcome of the appeal.

In cases that involve antitrust scrutiny, the parties may choose to defend the transaction or explore alternative methods of integration that do not involve the same level of antitrust implications. The alternatives include the formation of accountable care organizations and integrated provider networks. Accountable care organizations are specialized types of Medicare provider networks in which the healthcare providers coordinate care and share risk. There are many kinds of integrated provider networks. In general, they involve clinical and financial integration of the providers and thus some level of shared risk. These arrangements in general can involve less antitrust risk than outright acquisitions. Of course, it is also possible that transactions that do not trigger contemporaneous antitrust scrutiny by the government will involve antitrust risk. These risks must be assessed as part of the decision whether to proceed with the transaction.

Escrow, Installment Payments, and Earn Outs

Escrows and earn outs are common methods in acquisition transactions of protecting the buyer against the risk of misrepresentation or breach of warranty and protecting the buyer against the risk of overpaying. Installment payment offsets are less commonly used for the same purposes. In the context of physician practice acquisitions, however, where the buyer will be a recipient of referrals from the seller physicians, earn outs generally are to be avoided because of the need to comply with the Stark law and the AKS. The reason is that where the purchase price is in part dependent upon the post-closing performance of the practice, and the selling practice physicians will be employed post-closing, the presence of an earn out can result in the purchase price unlawfully taking account of post-closing referrals.

Escrows and installment payment offsets, on the other hand, can be acceptable means of reducing a buyer's risks. However, counsel should take care when drafting these provisions to avoid contingencies that could implicate the Stark law, the AKS, or parallel state laws. The critical issue is that escrow deductions and installment payment offsets should be based on breaches of representations and warranties that are not related to the financial performance of the practice after the closing of the purchase, but instead are related to breaches of representations and warranties that do not address post-closing financial performance.

Non-competes and Non-solicitation Agreements

As in the case of escrows and installment payment offsets, non-competes and non-solicitation agreements generally can be drafted so that they are acceptable from a regulatory standpoint. The Stark law and AKS do not prohibit exclusive relationships or non-competition agreements. Where the physicians will be employed post-closing and the purchaser is a healthcare provider or system to which the physicians will refer, the Stark law exception and AKS safe harbor for employment relationships need to be satisfied (whether or not non-competition agreements are used). Non-solicitation agreements in general do not raise regulatory issues under the Stark law or AKS.

11. *See* 42 U.S.C.S. § 1320a-7(b). **12.** *See* 42 C.F.R. § 1001.952(i). **13.** *See* 42 C.F.R. § 1001.952(e). **14.** *See* Saint Alphonsus Med. Ctr.-Nampa, Inc. v. Saint Luke's Health Sys., 2017 U.S. Dist. LEXIS 79940 (D. Idaho Apr. 27, 2017) (ordering the defendant hospital system to divest the acquired physician practice). **15.** *See* Federal Trade Com'n. v. Sanford Health, 2017 U.S. Dist. LEXIS 215937 (D.N.D. December 15, 2017).

In addition, non-competition agreements in general are enforceable under state law to the extent that they are reasonable in time and geographic scope,[16] although some states do not enforce non-competition agreements against employees at all.[17] Some states, by statute, prohibit the enforcement of non-competition agreements against physicians, even if reasonable non-competition agreements are enforceable in the context of other occupations.[18] Still other states, under case law, sometimes prohibit enforcement of non-competition agreements on the basis of the public interest in the availability of physicians.[19] Consequently, counsel should advise the buyer, in addition to the regulatory issues, to the enforceability of physician non-competition provisions in the relevant state.

Conclusion

In summary, physician practice acquisitions have much in common with corporate acquisition transactions generally. However, there are a number of additional considerations to be taken into account because of the significant regulation of healthcare. Key considerations include transaction structure, due diligence, purchase price and compensation, purchase price contingencies, and non-competes and other factors. Nevertheless, counsel can shepherd clients through successful practice acquisition transactions, thereby enhancing integration and clinical efficiencies and benefiting both providers and patients. L

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16. *See, e.g.*, Fla. Stat. Ann. § 542.335. 17. *See e.g.*, Cal. Bus. & Prof. Code § 16600. 18. *See, e.g.*, Del. Code Ann. tit. 6, § 2707 (although liquidated damages clauses may be enforceable); Mass. Gen. Laws ch. 112 § 12X. 19. *See, e.g.*, Emerick v. Cardiac Study Ctr., Inc., 286 P. 3d 689 (Wash Ct. App. 2012).

Related Content

For a sample agreement that can be used by an acquiring company that intends to hire or retain employees of the target company in connection with an acquisition, see

> **NON-COMPETITION, NON-SOLICITATION AND CONFIDENTIALITY AGREEMENT**

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For assistance in identifying the key antitrust topics that an attorney should consider when representing a client in a merger transaction, see

> **MERGER REVIEW ANTITRUST FUNDAMENTALS**

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For an outline of antitrust issues to consider at the various stages of an M&A transaction, see

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> **ESCROW AGREEMENTS IN PRIVATE M&A DEALS**

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Healthcare Providers and Insurers: **FTC Approach to Provider Mergers and Acquisitions**

This article explains how antitrust enforcers, primarily the Federal Trade Commission (FTC), analyze healthcare provider mergers, including hospital, outpatient, and physician-group mergers.

AFTER FEDERAL AND STATE ANTITRUST ENFORCERS LOST seven straight hospital-merger challenges in the 1990s, which put their hospital-enforcement approach in doubt, the FTC conducted a series of hospital merger retrospective studies that analyzed the competitive effects of several mergers. As a result of one of those studies, the FTC successfully challenged in its administrative court the consummated merger of Evanston Northwestern Healthcare and Highland Park Hospital. Since then, the FTC has won every fully litigated challenge to block or unwind a hospital and other healthcare provider merger, including several recent cases at the circuit court level. Additionally, in several non-litigated enforcement actions, the FTC has required remedies to approve the merger.

Legal Framework for Healthcare Provider Merger Analysis

Relevant Statutes

As with other mergers, Section 7 of the Clayton Act is the applicable antitrust statute for analyzing healthcare provider mergers.[1] Section 7 prohibits mergers and acquisitions "in any line of commerce . . . in any section of the country," where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." Although the U.S. Department of Justice (DOJ) and FTC both enforce Section 7, the FTC is responsible for the vast majority of merger investigations and enforcement actions involving healthcare providers. State attorneys general often join the FTC in its investigations and litigation. Moreover, while the FTC and DOJ typically seek to block transactions prior to consummation, Section 7 permits the agencies to challenge—and unwind—transactions post-consummation. Indeed, the FTC has successfully challenged several consummated healthcare provider mergers.

Section 7A of the Clayton Act, known as the Hart-Scott-Rodino (HSR) Act, requires merging parties, including healthcare providers, to notify the antitrust agencies and observe a 30-day waiting period prior to closing the merger if certain filing thresholds are satisfied.[2] An HSR filing gives the agencies a chance to review a merger before it is consummated, to avoid having to unscramble the eggs if the merger is ultimately deemed unlawful. Many healthcare provider mergers—either due to their relatively small size or the structure of the transaction—do not trigger an HSR-filing requirement. Importantly, however, the antitrust agencies can still investigate—and challenge—a transaction that does not require an HSR filing. Be aware that competing providers, insurers that contract with the merged providers, and state attorneys general often learn of transactions and alert the FTC to them. So even if a transaction is not reportable under the HSR Act, the FTC may still hear about and investigate the transaction if it raises competitive concerns, which might be more disruptive post-closing. Therefore, you should carefully consider whether to contact the FTC to inform the agency of a transaction, even if it is not reportable under the HSR Act, to avoid the FTC opening an investigation after the merger has closed.

Enforcement Actions

Over the last decade, several healthcare provider merger cases have been litigated to a decision. The FTC also has allowed several healthcare provider mergers to close, subject to consent orders that typically require a divestiture or other relief. The overview below explains the framework employed by the FTC and adopted by the courts deciding these cases. Counsel should be aware of these provider merger cases and enforcement actions.

Horizontal Merger Guidelines

The DOJ and FTC *2010 Horizontal Merger Guidelines* (Merger Guidelines)[3] are an important source for understanding the antitrust analysis of mergers and acquisitions. The agencies use the Merger Guidelines to analyze whether a merger may result in anticompetitive effects and, consequently, whether the agencies should take enforcement action. In particular, the Merger Guidelines explain how the agencies define relevant product and geographic markets, assess market shares and concentration, analyze evidence of a merger's competitive effects, and how they evaluate defenses and other mitigating factors. Although the Merger Guidelines are not binding on courts, several courts have cited to them as persuasive authority in healthcare provider merger cases.

Analytical Framework for Healthcare Provider Mergers

Framework for Healthcare Provider Competition

The FTC assesses provider competition and mergers under a framework called "two-stage competition." In stage one of this framework, healthcare providers compete to be included in insurers' health plan "provider networks." This competition largely focuses on price competition in that a provider negotiates with an insurer for inclusion in the insurers' provider network(s), and a key aspect of that negotiation is the reimbursement rates (i.e., prices)

1. 15 U.S.C.S. § 18. 2. 15 U.S.C.S. § 18a. 3. https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf.

that the insurer will pay to the provider. In this framework, the relative bargaining leverage of the provider and the insurer largely determines the outcome of that price negotiation. The more leverage a provider has, the more likely that it can negotiate for higher rates; conversely, the more leverage the insurer has, the more likely that it can resist rate increases. The FTC is concerned about provider mergers that substantially lessen competition because that may provide the merged firm with enhanced bargaining leverage and enable it to extract higher prices. On the other hand, if merged providers' bargaining leverage with insurers would not substantially change after the transaction because, for example, there would be adequate alternatives to which the insurer could turn, then the transaction is unlikely to raise competitive concerns.

In stage two, healthcare providers that are included in an insurer's provider network (i.e., in-network providers) compete for patients. The FTC views this competition as largely occurring on non-price dimensions, such as quality of care and amenities, because insured patients generally pay the same out-of-pocket costs regardless of which in-network provider they use, so competition for patients largely occurs on non-price dimensions. The FTC is concerned about the potential for a transaction to reduce the merged providers' incentive to maintain or improve quality of care.

Antitrust Analysis of Healthcare Provider Mergers

Court decisions and the FTC's filed complaints in provider mergers show that the analysis generally follows the Merger Guidelines approach and structure. Specifically, the FTC alleges and courts analyze:

- The relevant product and geographic markets
- The combined firm's market share and market concentration
- Other evidence of the competitive effects of the merger
- The defenses raised by the merging parties, including entry, efficiencies, and the failing-firm defense

In investigations, the FTC also considers any immunities and safe harbors that may apply.

Conduct a preliminary merger analysis that assesses the key factors that the FTC will investigate, such as product and geographic market definitions and post-merger market shares and concentration, including in narrowly defined markets.

Healthcare providers integrate through a variety of structures, including mergers, acquisitions, affiliations, and membership substitution agreements. Whatever the terminology, the antitrust enforcers are likely to analyze the transaction as a merger if the effect of the transaction is equivalent to a merger. Therefore, antitrust enforcers analyze joint ventures and other collaborations that meet four criteria—essentially, the collaboration involves significant, long-term integration that eliminates all competition between the parties in a relevant market under the Merger Guidelines.[4] Beyond these broad criteria, there is no clear and definitive agency guidance on when a collaboration effectively constitutes, and is analyzed as, a merger.

To the extent a joint venture, loose affiliation, or other collaboration does not constitute a merger, however, courts and antitrust enforcers instead will analyze the collaboration under Section 1 of the Sherman Act, which makes unreasonable restraints of trade unlawful.

Finally, the agencies analyze the formation of accountable care organizations (ACOs) under guidance specific to ACOs and distinct from the Merger Guidelines.[5]

The following sections discuss the FTC's antitrust analysis in mergers involving hospitals, outpatient providers, and physician groups. The analysis is very similar across these types of provider mergers, but any material differences are discussed below. Several courts, including the U.S. Courts of Appeals for the Third, Sixth, Seventh, and Ninth Circuits, have ruled in favor of the FTC in its recent cases challenging provider mergers—specifically hospital and physician-group mergers—and in doing so these courts largely adopted the FTC's analytical approach. Therefore, when counseling clients involved in a healthcare provider merger, you should be familiar with these cases and assume that the FTC—and courts—will take this approach in transactions that come before them, unless convinced otherwise.

Defining the Relevant Product Market

Hospital Mergers

The product market in hospital cases is typically inpatient general acute care (GAC) hospital services sold to commercial health plans. For antitrust purposes, product markets are defined around products and services that are substitutable for one another. Individual hospital services are not substitutes for another (e.g., neurosurgery cannot be substituted for cardiac surgery), so each inpatient hospital service could be its own separate product market for antitrust purposes. But since hospital mergers generally involve dozens, if not hundreds, of overlapping inpatient hospital services, it is often not practical to separately analyze (or litigate) so many markets. Therefore, the FTC alleges—and courts have accepted—the inpatient GAC hospital services cluster market. A cluster market is a product market consisting of multiple, non-substitutable products or services, which are included in a single product market for analytical and administrative convenience when the competitive conditions—such as the number of competitors and entry conditions—are similar for the products or services included in the cluster market.

The FTC includes in the GAC hospital services market only inpatient services that both merging parties offer; it excludes services that only one of the merging parties offers. Moreover, despite more hospital care moving to an outpatient setting and hospitals often bargaining with insurers over both inpatient and outpatient services in the same negotiation, the FTC's inpatient GAC services market definition excludes outpatient services because patients (and their physicians) do not substitute outpatient services for inpatient services in response to price increases.

In addition to the inpatient GAC product market, the FTC may also allege a separate inpatient market for individual hospitals' services where the competitive conditions for a service differ meaningfully from the overall inpatient GAC market. You might see this where there are fewer competitors offering that individual service and the merging parties' market share in that service is meaningfully higher than in the inpatient GAC market. Therefore, you should assess whether there are any overlapping inpatient services where the parties' combined market share, and where market concentration, is significantly higher.

Outpatient Mergers

In outpatient services, the FTC has defined the relevant product market as a cluster of one or more outpatient service lines—that is, services that do not require an overnight hospital stay or that require less than a 24-hour stay. The FTC has alleged an array of relevant product markets in outpatient mergers, such as outpatient surgical services, outpatient orthopedic surgical services, and outpatient ear, nose, and throat surgical services.[6] Notably, the FTC has included outpatient services in the same product market regardless of the type of facility (i.e., freestanding ambulatory surgery center, hospital, or specialty hospital) that provides the service.

Physician-Group Mergers

The FTC has defined product markets in physician-group mergers as a cluster of one or more specialty physician service lines. The FTC defines markets around specific physician specialty areas based on several factors, including, for example:

- Specific training in a specialty
- The setting in which the service is provided (e.g., hospital-only versus outpatient)
- Patient preference to seek certain medical services from specialists (e.g., obstetrics/gynecology (OB/GYN) services)

In recent enforcement actions, the FTC has alleged, and courts have found, relevant product markets consisting of adult primary care physician (PCP) services, OB/GYN services, pediatric services, adult cardiology services, orthopedic physician services, and general surgery physician services.

Defining the Relevant Geographic Market

Geographic market definition is often one of the most difficult and contested issues in a provider-merger investigation and litigation. The FTC typically defines the geographic market in provider mergers as a relatively narrow local market. For example, in recent enforcement actions, the FTC has defined geographic markets as narrowly as a county or portions of two counties, and as broadly as multi-county areas around merging hospitals. The agency considers a range of qualitative and quantitative evidence from the merging parties and third parties to define the geographic market, but it pays special attention to the views of, and evidence from, insurers because they are deemed to be the direct purchasers of healthcare provider services. The analysis and relevant evidence in geographic market definition are essentially the same in hospital, outpatient, and physician mergers.

In terms of qualitative evidence, the FTC evaluates testimony and documents from the merging providers and area insurers, rival hospitals, and employers about several factors in defining the geographic market. Among other things, the FTC reviews available evidence about how the merging parties define their service areas and calculate market shares in the ordinary course of business; which providers compete meaningfully with the merging parties; and where (to which providers) most local residents go for healthcare services, taking into account any geographic or topographical barriers (e.g., state lines, rivers) that affect where patients go.

In terms of quantitative evidence, the FTC may calculate diversion ratios and conduct a hypothetical monopolist test. Diversion ratios calculate the percentage of patients who would turn to each other alternative provider if the patients' first-choice provider was unavailable. If diversion ratios show that a meaningful percentage of the merging parties' patients would switch to a particular provider, that provider is more likely to be in the geographic market.

In full-phase investigations and matters heading for litigation, the FTC will likely employ the hypothetical monopolist test, especially after the U.S. Court of Appeals for the Seventh Circuit[7] and the U.S. Court of Appeals for the Third Circuit[8] both affirmed that the test was an appropriate way to define geographic markets in hospital-merger cases. The test asks whether a hypothetical monopolist of providers (e.g., all hospitals) in a candidate geographic market could profitably impose a small but significant and non-transitory increase in price (SSNIP), which is usually defined as a 5%–10% price increase, on insurers. If so—because insurers could not offer patients a viable network with only providers outside the candidate market—that area constitutes a relevant geographic market. If not—because insurers could turn to providers outside the candidate market to form a viable provider network—then

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For a general background on the merger review process, see

> **MERGER REVIEW ANTITRUST FUNDAMENTALS**

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For a summary of recent healthcare provider merger cases and other enforcement actions, see

> **HEALTHCARE PROVIDERS AND INSURERS: HEALTHCARE PROVIDER MERGER ENFORCEMENT ACTIONS CHART**

RESEARCH PATH: *Antitrust > Mergers and Acquisitions > Merger Analysis > Practice Notes*

For an analysis of the investigative methods the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) employ to conduct substantive reviews of proposed merger transactions, see

> **DOJ/FTC MERGER INVESTIGATION PROCESS**

RESEARCH PATH: *Antitrust > Mergers and Acquisitions > Antitrust Investigations > Practice Notes*

4. *See* FTC and DOJ, *Antitrust Guidelines for Collaboration Among Competitors* § 1.3, https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf. **5.** *See* 76 Fed. Reg. 67,026 (2011).

6. *See, e.g.*, In re H.I.G. Bayside Debt & LBO Fund II, L.P., 2014 FTC LEXIS 282 (F.T.C. Oct. 31, 2014); In re Reading Health Sys., 2012 FTC LEXIS 177 (F.T.C., Nov. 16, 2012). **7.** FTC v. Advocate Health Care Network, 841 F.3d 460 (7th Cir. 2016). **8.** FTC v. Penn State Hershey Med. Ctr., 838 F.3d 327 (3d Cir. 2016).

the candidate geographic market is deemed too narrow and it is broadened until the test is satisfied.

Because the FTC does not necessarily perform a formal econometric calculation of the hypothetical monopolist test during investigations, FTC staff generally seeks qualitative evidence that mimics the test. Specifically, FTC staff assesses whether commercial insurers could offer a marketable health plan to area employers and individuals in the candidate market if the insurer's health plans excluded all of the providers in a candidate geographic market. If so, that suggests that insurers could offer a viable network with providers outside the candidate market and, thus, the area does not satisfy the hypothetical monopolist test and the candidate market should be broadened. If insurers could not market a viable network without the providers in the candidate market, or if insurers would pay higher prices to offer a network that included the providers in the candidate market, this suggests that the area satisfies the hypothetical monopolist test and constitutes a relevant geographic market.

Market Shares and Concentration

Under case law and the Merger Guidelines, transactions that result in a high combined market share for the merged firm, result in a concentrated market, and leave few remaining competitors raise the most significant antitrust risk. To assess these factors, the FTC typically looks at the combined share of the merging providers and calculates market concentration levels using the Herfindahl-Hirshman Index (HHI).

In *United States v. Philadelphia National Bank*, the Supreme Court set a rebuttable presumption of illegality when a merger yields a combined market share of 30% or more, which the FTC cites in litigated cases.[9] The FTC's recent provider-merger challenges, however, have involved mergers where the parties' combined share is well above that level. In *Reading Health Systems*, for example, the merger would have resulted in the merged firm having between a 48% and 71.5% share across various service lines. Note that if a merger results in a combined share above 30%, the chances of an in-depth investigation or an enforcement action may increase but shares above 30% do not necessarily mean that the agency will bring an enforcement action.

As such, calculating market shares is one tool you should use to assess the potential for FTC scrutiny in a provider merger. As a starting point, you should identify how the merging parties calculate market shares in the ordinary course of business. You should also try to determine whether the FTC could plausibly identify any narrower markets (e.g., an individual service line or a narrow geographic area) that would result in high shares.

Markets shares are calculated in different ways depending on the type of provider merger:

- In hospital mergers, the FTC typically calculates market shares using patient admissions (or discharges) and sometimes patient days.
- In outpatient-provider mergers, the FTC has calculated market shares using the number of procedures performed.
- In physician-group mergers, the FTC typically calculates market shares using physician headcount, but it has also calculated them using patient visits or volumes.

Another tool to assess the risk of FTC scrutiny is to calculate pre- and post-merger market concentration levels. Under the Merger Guidelines, transactions that increase the HHI by more than 200 points and result in a post-merger HHI of more than 2,500 are presumed to enhance market power and, thus, are likely to result in close FTC scrutiny. Transactions that do not result in a highly concentrated market, or that increase market concentration only slightly, are less likely to receive close scrutiny.

Competitive Effects

The ultimate antitrust question in any merger is what effect, if any, it will have on competition. In a provider merger, the primary question is whether the transaction is likely to result in higher prices or a diminished incentive to maintain or improve quality of care. In particular, the FTC will evaluate whether the combination is likely to give the merged providers enhanced bargaining leverage in negotiations with insurers. If so, that may enable the merged providers to negotiate higher reimbursement rates, either because insurers could not market a viable network without the merged firm or because they would pay a higher price to keep the merged provider in-network. The FTC also evaluates whether competition between the merging providers has spurred each to improve quality, offer new services, and otherwise improve patient care, which would be lost as a result of merger.

To assess the likely competitive effects of a provider merger, the FTC uses a variety of qualitative and quantitative evidence from the merging parties, insurers, competing providers, employers, and any other relevant third parties. Such evidence includes:

- Documents from the merging parties assessing who their closest competitors are and efforts to compete against their merger partner, such as documents that discuss responding to the other merger partner in terms of prices, adding new services or equipment, recruiting physicians, opposing the other's efforts to obtain certificate of need (CON) approvals, and comparative marketing and advertising materials, especially as they relate to quality and services offered.
  - Many states require CON approval, which assesses demand or need in a given area, prior to the construction or expansion of a healthcare facility (or acquisition of certain equipment).
- Documents and testimony regarding the merging providers' negotiations with insurers over reimbursement rates and inclusion in insurers' networks, including any efforts by either of the merging parties to have insurers exclude the other merger partner from the insurers' networks, or to offer lower reimbursement rates if insurers exclude the merger partner from their networks.
- Documents and testimony about whether insurers have ever offered a health plan that excluded both of the merging parties, or whether insurers believe they could do so after the merger.
  - If insurers have not and could not do so, this suggests that the merged providers could have increased bargaining leverage to demand higher prices.
  - If insurers have offered or could offer a marketable network without the merging providers, this significantly reduces antitrust risks.
- Documents and testimony about the value that employers and their employees place on having the merged firm in their insurer's provider networks and whether employees would be willing to use other providers if the merged providers were not in-network.
- Data, particularly detailed state and insurers' hospital discharge and other data, which the FTC may use to calculate and refine diversion ratios and market shares; calculate a willingness-to-pay model, which measures the value that consumers place on having particular hospitals in their insurer's networks; and conduct a merger simulation, which models the likely effects of the merger on prices.

As counsel for the merging parties, you should speak with executives of your client and review documents that address the topics above. Understanding whether the merging providers are two close competitors with few or no attractive alternatives for insurers and patients to turn to will illuminate whether the transaction is likely to raise competitive concerns. Additionally, because commercial insurers—as the direct customers of providers and viewed as proxies for employers and patients—are generally the key witnesses in provider-merger investigations and litigations, you should seek to understand how insurers would view the transaction and the history

9. 374 U.S. 321 (1963).

of provider-insurer negotiations in that geographic area. Moreover, your provider client should speak with its commercial insurance partners about the transaction before it is announced—or at least before the FTC contacts the insurer—to explain the benefits of the transaction and assess whether they have any concerns about the merger. Finally, for transactions raising meaningful risk of antitrust scrutiny, you should consider hiring an economic consultant specializing in healthcare to analyze the discharge data and other aspects of the transaction.

Defenses

The most direct way for a merger to clear antitrust review is to convince the agency that the merger does not harm competition, either because the parties are not in the same geographic market, there are a sufficient number of other significant competitors that will remain in the market, or the merging providers do not otherwise compete meaningfully.

Additionally, merging parties can raise a variety of defenses and mitigating factors to overcome potential FTC concern, including:

- Entry or expansion
- Efficiencies
- Failing- or flailing-firm (weakened-competitor) defenses
- State action immunity
- A safe harbor

Although these defenses can convince the FTC to close investigations, the first three defenses have not succeeded in recently litigated cases. Therefore, your best opportunity to secure merger clearance is to convince staff early on in an investigation that there is no likelihood of competitive harm or that one of your defenses outweighs any potential harm.

Entry

To establish the entry defense under the Merger Guidelines, entry must be timely, likely, and sufficient to offset the competitive harm. The FTC has generally found that healthcare provider entry is unlikely to be timely and sufficient because of regulatory and licensing requirements, as well as the time and cost necessary to build or expand facilities, recruit physicians, and develop sufficient patient volumes to replicate the lost competition. Moreover, if the merger occurs in a state with a CON law, that is likely to make an entry defense particularly challenging, given the length of time and/or difficulty to get CON approval. If you do pursue this defense, the best evidence to present is likely to be any examples of recent entry or already-announced imminent entry in the market at issue. Examples of recent entry can show that entry is feasible despite potential barriers, although counsel should consider whether that might make additional future entry less likely. Examples of already-announced imminent entry can help show that any post-merger increase in concentration will be offset by forthcoming entry, if such entry will be of sufficient scale.

Efficiencies

Providers often seek to merge to achieve various efficiencies, such as improving quality of care, achieving cost savings, and engaging in risk-based contracting and population health management. Quality is often the most significant efficiency that the FTC focuses on. But convincing the FTC that efficiencies outweigh potential competitive harm is challenging. To do so, you must show that the efficiencies are merger-specific, meaning that they could not be achieved without the merger; are substantiated, meaning verifiable and not speculative; outweigh the competitive harm; and that the benefits of these efficiencies will be passed on to consumers.

While the efficiencies defense has not rescued an otherwise anticompetitive provider merger in court, merging providers have successfully convinced the FTC to close merger investigations at least in part on this basis. Therefore, there are steps you can take to increase your chances of successfully making an efficiencies defense. First, although it can be costly, you should consider whether to hire an efficiencies consultant or expert to help assess and substantiate any claimed efficiencies, at least in transactions that are likely to raise competitive concerns. Second, although it is not an element of the efficiencies defense, the merging parties' efficiencies claims will be more credible if they document that efficiencies were a driving force for doing the transactions, as opposed to a last-minute justification for the FTC to approve the deal. Finally, efficiency claims may be more convincing when the target firm is under financial duress, quality may be compromised absent the transaction, and the parties combine their efficiencies claims with a failing- or flailing-firm defense, as described below.

Failing-Firm and Flailing-Firm (Weakened-Competitor) Defenses

The failing-firm defense applies where the target firm is at imminent risk of exiting the market due to its dire financial condition and it has made a good faith but unsuccessful effort to find an alternative acquirer that raises less competitive concern. Case law and the Merger Guidelines recognize the defense. The flailing-firm, or weakened-competitor, defense relates to firms in slightly less dire situations than failing firms and essentially posits that the financial condition of the target firm is weakened enough that its current competitive position and market share overstates its future competitive significance. The defense is also known as the *General Dynamics* defense, after the Supreme Court decision that recognized it.[10] However, unlike the failing-firm defense, the Merger Guidelines do not explicitly recognize the weakened competitor defense, and the United States Court of Appeals for the Sixth Circuit in *ProMedica Health Sys. v. FTC* reiterated the high bar to establishing this defense.[11]

Still, the failing-firm defense has worked in certain cases. In *In re CentraCare Health System*, for example, the FTC accepted the defense where the target physician practice group had been unable to find an alternative purchaser for the entire practice and the FTC was concerned about disruptions to patient care and physician departures from the local area if the transaction was blocked.[12] The FTC approved the merger, subject to the merged firm releasing a certain number of physicians from noncompete agreements so that they could work in other medical groups in the community.

In another instance, the FTC closed its investigation of Scott & White Healthcare's acquisition of financially troubled King's Daughters Hospital, based on the failing-firm defense. The FTC focused on whether an alternative purchaser had been deprived of an opportunity to conduct due diligence and remained interested in acquiring King's Daughters. If so, King's Daughters would be sold to the alternative purchaser on specific terms. As it turned out, the alternative purchaser was not interested in acquiring the troubled hospital, and the FTC allowed Scott & White to complete its acquisition of King's Daughters.[13]

To establish the failing-firm defense, you should marshal as much evidence and data as possible about the deteriorating financial and operational condition of the target firm. The defense is more likely to succeed if you can show, for example:

- Persistently and steeply declining revenues, profits, days cash on hand, admissions/procedures/patient volume, and capital expenditures
- Increasing debt, pension obligations, and other unfunded liabilities
- Operational challenges, such as closing service lines and physician departures

You should also demonstrate that the target firm conducted a thorough search for an alternative purchaser and that none exists. It can be helpful to show that a consultant or investment banker conducted or aided the search. If, however, the search was limited either in scope or duration, or potentially interested and credible buyers were otherwise dismissed (e.g., because their bid was lower), that can hinder or prevent you from establishing the defense.

State Action Immunity

State governments have the power to shield mergers from federal antitrust liability under the state action doctrine. For the immunity to apply, the state must clearly articulate and affirmatively express an intent to displace competition and replace it with a state regulatory regime, and actively supervise the otherwise anticompetitive transaction.[14]

10. U.S. v. General Dynamics Corp., 415 U.S. 486, 503–04 (1974). **11.** 749 F.3d 559, 572 (6th Cir. 2014). **12.** 2016 FTC LEXIS 185 (F.T.C. Oct. 5, 2016). **13.** *See* FTC, *Statement of the Director of the Bureau of Competition, In re Scott & White Healthcare*, https://www.ftc.gov/sites/default/files/documents/closing_letters/scott-white-healthcare/kings-daughters-hospital/091223scottwhitestmt.pdf. **14.** *See* FTC v. Phoebe Putney Health Sys., Inc., 568 U.S. 216 (2013).

Related Content

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> **HORIZONTAL MERGER ANALYSIS**

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For more information on unreasonable horizontal restraints agreed to by competitors, see

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RESEARCH PATH: *Antitrust > Horizontal Agreements with Competitors > Practice Notes*

For a detailed discussion on the Hart-Scott-Rodino Act filing requirements, see

> **REPORTABILITY OF A MERGER OR ACQUISITION UNDER THE HART-SCOTT-RODINO (HSR) ACT**

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For additional information on the key issues to consider with respect to defining a market for antitrust merger analysis, see

> **MARKET DEFINITION**

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For assistance in representing a healthcare client in federal antitrust litigation by utilizing the state-action immunity doctrine, see

> **STATE-ACTION IMMUNITY IN ANTITRUST CASES**

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States typically effectuate the state action doctrine with respect to provider mergers by passing legislation stating an intent to displace healthcare provider competition and replace it with a system under which merging providers can apply for a certificate of public advantage (COPA) or cooperative agreement (CA). Under a COPA or CA regime, the state reviews an application from the merging parties, and may conduct public hearings and accept public comments on the transaction. If the benefits of the transaction—in light of any commitments that the merging parties make to cap price increases and make quality- and health-improving investments in the community—outweigh the potential disadvantage from the transaction, the state can approve the transaction and COPA/CA, subject to ongoing state supervision.

Recently, merging providers successfully used the COPA/CA process to close two mergers despite FTC opposition. The first was the merger of Cabell Huntington Hospital and St. Mary's Medical Center in West Virginia. The second was the merger of Mountain States Health System (MSHA) and Wellmont Health System (Wellmont) in Tennessee and Virginia. Although the FTC did not explicitly acknowledge that state action immunity applied in those cases, its decision not to challenge these mergers and its closing statement in the Cabell/St. Mary's matter suggest that it believed that the immunity did apply or at least raised significant litigation risk if it were to try to block these transactions in court.

You should note that while the COPA/CA can ultimately provide immunity from antitrust liability, seeking or even obtaining a COPA/CA does not necessarily immunize parties from an FTC investigation. Moreover, you should know that the COPA/CA process can be lengthy. MSHA and Wellmont pursued their COPA for approximately two years before the relevant state bodies approved the COPA/CA and the transaction closed. Finally, operating the merged provider under an approved COPA can be burdensome. As a condition of approval, MSHA and Wellmont agreed to abide by a substantial number of conditions, which an independent monitor will track.

Safety Zone

In 1996, the FTC and DOJ jointly published "Statements of Antitrust Enforcement Policy in Healthcare" (Health Statements). Though dated, antitrust counsel still use the Health Statements because they provide guidance on the agencies' enforcement policies in healthcare. Of relevance to provider mergers, "Statement 1" provides a safety zone from antitrust enforcement for certain hospital mergers. Statement 1 states that hospital mergers that fall under the safety zone will not be challenged absent extraordinary circumstances. This safety zone applies to mergers of two general acute care hospitals where one of the hospitals has had an average of fewer than 100 licensed beds over the three most recent years and an average daily inpatient census of fewer than 40 patients over the three most recent years. The exemption does not apply if that hospital is less than five years old, however. You should also note that the safety zone does not apply to non-GAC hospitals, such as specialty hospitals or to other types of providers.

Mitigating Antitrust Risk in Provider Mergers

The following are potential ways to identify and minimize antitrust risks in healthcare provider mergers:

- Conduct a preliminary merger analysis that assesses the key factors that the FTC will investigate, such as product and geographic market definitions and post-merger market shares and concentration, including in narrowly defined markets. If your transaction triggers the market share or concentration presumptions, be prepared for additional scrutiny and to explain why the presumptions are incorrect.
- Review ordinary-course documents and the Item 4 documents that will be submitted with the HSR filing (or similar types of documents, if no HSR filing is required) to see how competition, competitors, the effects of the transaction, and efficiencies are viewed and discussed. Provocative language in documents submitted to the agency will likely trigger greater scrutiny, so be prepared to explain why any such material is inaccurate.
- Interview senior executives to understand how they view the market, competition, and competitors in the ordinary course of business. In particular, interview the person responsible for negotiating contracts with insurers to see what the history of those negotiations has been, how insurers' providers networks in the area have been configured, and the anticipated reaction by insurers to the transaction.
- Substantiate the potential efficiencies stemming from the deal and why such efficiencies cannot be achieved—at all, or as quickly or to the same extent—without the transaction. If one or both of the merging parties have been unable to achieve efficiencies independently or through collaborations short of a merger, document those failed efforts. Likewise, if a merging party has achieved efficiencies from prior mergers and acquisitions document that successful track record.
- Prior to notifying the FTC about the transaction, consider having your client contact the largest insurers they contract with, and the largest employers in the area, to explain why the transaction is procompetitive.

The following are additional ways to identify and mitigate antitrust risk if a provider merger is likely to be investigated or is under agency review.

- If you have a strong basis for explaining away potential competitive concerns, consider engaging FTC staff early on. Addressing bad facts up front and providing staff with the necessary context to explain why those facts are not fatal to your transaction will often be a better approach than hoping staff disregards bad facts or does not discover them.

- Engage with FTC staff frequently, ask where they are in their analysis, and offer assistance. This engagement and assistance provides counsel with an opportunity to gain insight into staff's thinking, addresses potential concerns they may have, and could help speed up the review.
- Do not misrepresent facts. Exaggerating and withholding information are also generally not successful strategies, both because staff is adept at verifying the accuracy of claims and finding answers and because it will diminish your credibility.
- Be respectful to FTC staff. Especially in the first 30 days of an investigation—before a recommendation has been made on whether to issue a Second Request (i.e., a giant subpoena for documents, data, and other information, which extends the HSR Act waiting period)—agency staff is the key judge and jury, and convincing them early on that your merger does not substantially lessen competition represents your best chance to have the transactions cleared without incurring the substantial time and cost involved with a full-phase investigation. L

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RESEARCH PATH: *Antitrust > Mergers and Acquisitions > Merger Analysis > Practice Notes*

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Wellness Program Design and Compliance

EMPLOYER-SPONSORED WELLNESS PROGRAMS HAVE become increasingly common as employers attempt to control rising healthcare costs and improve employees' overall health and productivity.

Designing and operating a wellness program requires careful consideration of compliance obligations under a number of different laws including, but not limited to, the Employee Retirement Income Security Act of 1974 (ERISA), the Internal Revenue Code of 1986 (Code), the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Patient Protection and Affordable Care Act of 2010 (ACA), the Genetic Information Nondiscrimination Act of 2009 (GINA), and the Americans with Disabilities Act of 1990 (ADA).

This article discusses how to design and operate compliant wellness programs, with a particular focus on HIPAA, ACA, GINA, and ADA requirements. The following topics are specifically addressed in this article:

- Characterization of wellness programs
- HIPAA non-discrimination requirements
- ACA requirements
- GINA requirements
- ADA requirements
- Other legal requirements
- Common pitfalls
- Importance of periodic wellness program reviews

Characterization of Wellness Programs

The first step in assessing the compliance obligations that apply to a particular wellness program is to determine whether the program is itself a group health plan or is part of a group health plan.

Wellness Programs that Provide Medical Care

An employer-sponsored wellness program is a group health plan if it provides medical care, which is defined as (1) amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body; (2) amounts paid for transportation primarily for and essential to medical care referred to in clause (1); and (3) amounts paid for insurance covering medical care referred to in clauses (1) and (2). Examples of medical care include biometric screenings (including cholesterol screenings), physical examinations, flu shots, counseling by trained professionals, and other programs that are diagnostic or preventive, or coaching individuals regarding specifically identified health risks.

A wellness program that simply promotes good health and a healthy lifestyle likely does not provide medical care. Examples of wellness programs that promote good health and a healthy lifestyle, but which do not provide medical care, include programs that reimburse all or part of the cost for membership in a fitness center or that provide general educational information about how to maintain a healthy diet and exercise regimen.

An employer that sponsors a wellness program that provides medical care must decide whether to structure the program as a stand-alone group health plan or as part of another group health plan sponsored by the employer, such as the employer's major medical plan. A stand-alone group health plan structure may be warranted if the employer wants to offer the wellness program to all employees, not just employees eligible for the employer's major medical plan. However, structuring the wellness program as a stand-alone group health plan requires the wellness program to comply with all legal requirements applicable to group health plans under ERISA, the Code, COBRA, HIPAA, the ACA, GINA, and the ADA (collectively, the Group Health Plan Mandates) on its own. Structuring the wellness program as part of the employer's major medical plan allows the wellness program to piggyback on the medical plan's compliance with the Group Health Plan Mandates.

Wellness Programs that Are Part of a Group Health Plan

Even if a wellness program does not provide medical care, the program might still have to comply with the Group Health Plan Mandates if it is part of another group health plan. Examples of instances in which a wellness program may be part of another group health plan include the following:

- The group health plan contracts for the wellness program.
- The reward for participating in the wellness program (or the penalty for not participating in it) impacts cost sharing under the group health plan (e.g., reduction in or increase to the employee contribution rate, deductible, co-payment, coinsurance, and/or annual maximum).
- The wellness program is promoted as part of the group health plan.

A wellness program that is part of another group health plan should be able to rely on the group health plan's compliance with the Group Health Plan Mandates as its own compliance with such requirements. However, the employer or plan sponsor must ensure compliance with the legal requirements specifically applicable to wellness programs as described in further detail below.

Wellness Programs that Do Not Provide Medical Care and Are Unrelated to a Group Health Plan

If a wellness program does not provide medical care and is not otherwise part of another group health plan, the program does not have to comply with most of the Group Health Plan Mandates described in this article. Rather, the employer or plan sponsor of such a program must ensure that the program complies with generally applicable employment laws such as Title II of GINA, the ADA's general prohibition on discrimination against disabled

individuals, the Age Discrimination in Employment Act of 1967, Title VII of the Civil Rights Act of 1964, and the Fair Labor Standards Act of 1938 when providing the program as a general term, condition, or privilege of employment. For example, if a wellness program provides a $50 gift card as a reward for completing a health risk assessment (HRA) or attending a health fair that provides general information, the program is not subject to the Group Health Plan Mandates because it is not providing medical care, does not offer a reward that impacts cost sharing under a group health plan, and is not otherwise part of another group health plan.

HIPAA Non-discrimination Requirements

A wellness program that is itself a group health plan or is part of a group health plan must comply with non-discrimination requirements under HIPAA. The ACA codified existing HIPAA non-discrimination requirements for wellness programs, and federal agencies issued final regulations in 2013.[1] HIPAA generally prohibits a group health plan from discriminating among similarly situated individuals based on their health status (e.g., group health plans generally cannot charge individuals different premiums based on a health factor), but creates an exception to these non-discrimination provisions for certain wellness programs. To qualify for the exception to HIPAA's general non-discrimination provisions, a wellness program that is itself a group health plan or is part of a group health plan must be structured to comply with the applicable requirements of the HIPAA Wellness Program Regulations.

The HIPAA Wellness Program Regulations recognize two broad categories of wellness programs: participation-only programs and health-contingent programs.

Participation-Only Programs

A participation-only program is a program that does not condition eligibility for a reward on the participant's ability to meet a particular health standard. Examples of participation-only programs include completion of an HRA, health education sessions, or health coaching, and participation in a biometric screening without requiring that any particular biometric targets be attained. For a participation-only program to comply with the HIPAA Wellness Program Regulations, participation in the program must be available to all similarly situated individuals regardless of health status.

In determining groups of similarly situated individuals, the following distinctions are permissible:

- Participants and beneficiaries can be treated as two different groups of similarly situated individuals.
- Individuals enrolled in different benefit package options can be treated as different groups of similarly situated individuals.
- Participants can be treated as two or more different groups of similarly situated individuals based on bona fide employment-based classifications consistent with the employer's usual business practice, such as:
  - Full-time versus part-time status
  - Different geographic locations
  - Membership in a collective bargaining unit
  - Date of hire
  - Length of service
  - Current employee versus former employee status
  - Different occupations
- Beneficiaries can be treated as two or more different groups of similarly situated individuals if the distinction is based on:
  - A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage
  - A relationship to the participant (e.g., as a spouse or as a dependent child)
  - Marital status
  - With respect to children of a participant, age, or student status
  - Any other factor that is not a health factor

Participation-only wellness programs can vary from group to group of similarly situated individuals, as long as whatever program is offered to a particular group is available to all of the individuals in that group regardless of health status. For example, the opportunity to earn a reward by completing an HRA could be offered to full-time employees only, but that opportunity would have to be offered to all full-time employees and not just full-time employees who have never been diagnosed with heart disease.

Note that more favorable rules can be established for individuals with adverse health factors than for individuals without such adverse health factors, so it is permissible to discriminate in favor of individuals with an adverse health status. For example, the opportunity to earn a reward by participating in a health coaching session could be offered only to employees who have high blood pressure.

Health-Contingent Programs

A health-contingent program is a program that conditions eligibility for a reward on a participant's ability to meet a standard related to a health factor. There are two types of health-contingent programs under the HIPAA Wellness Program Regulations: (1) activity-only programs and (2) outcome-based programs.

1. HIPAA Wellness Program Regulations, 78 Fed. Reg. 33,158 (June 3, 2013) (codified at 26 C.F.R. § 54.9802-1; 29 C.F.R. § 2590.702).

An activity-only program is a program that requires an individual to perform or complete an activity related to a health factor to obtain a reward, but does not require the attainment or maintenance of a specific health outcome. Examples of activity-only programs include walking, diet, and exercise programs. An outcome-based program is a program that requires an individual to attain or maintain a specific health outcome, such as attaining a specific body mass index or cholesterol level.

For either an activity-only or outcome-based health-contingent program to comply with the HIPAA Wellness Program Regulations, it must satisfy the five requirements outlined below. The actions necessary to comply with each of these five requirements may vary depending on whether the health-contingent program is an activity-only program or an outcome-based program.

1. Individuals must have an opportunity to qualify for the reward at least once per year.
2. The sum of the reward(s) for all health-contingent wellness programs with respect to a plan must be no more than 30% of the total cost of coverage (50% in the case of a program to prevent or reduce tobacco use), which is determined in accordance with the following:
   - The cost of coverage is the total employer and employee contributions for the group health plan or group health plan option in which the employee and, if applicable, the employee's dependents, are receiving coverage.
   - If only the employee can participate in the wellness program, the cost of employee-only coverage is used to determine the total cost of coverage.
   - If the employee and dependents can participate in the wellness program, the cost of coverage in which the employee and dependents are enrolled is used to determine the total cost of coverage.
3. The program must be reasonably designed to promote health or prevent disease, which means the program:
   - Has a reasonable chance of improving health or preventing disease
   - Is not overly burdensome
   - Is not a subterfuge for discrimination based on a health factor
   - Is not highly suspect in the method chosen to promote health or prevent disease

4. The full reward must be available to all similarly situated individuals, as follows:
   - For an activity-only program, the reward is available if the program provides a reasonable alternative standard as another means by which to earn the same reward for any individual for whom it is either (1) unreasonably difficult due to a medical condition to satisfy the standard, or (2) medically inadvisable to attempt to satisfy the standard (if reasonable, the program can seek verification from the individual's personal physician that a health factor makes it unreasonably difficult or medically inadvisable for an individual to satisfy, or attempt to satisfy, the particular standard).
   - For an outcome-based program, the reward is available if the program provides a reasonable alternative standard as another means by which to earn the same reward, regardless of whether it is unreasonably difficult due to a medical condition or medically inadvisable to attempt to satisfy the standard, and it is never reasonable to seek verification that a health factor makes it unreasonably difficult or medically inadvisable to satisfy, or attempt to satisfy, the particular standard.
   - For an alternative standard under either an activity-only program or an outcome-based program to be reasonable, (1) the alternative must have a reasonable time commitment; (2) if the alternative is completion of an educational program, the program must help the individual find the educational program and cannot charge the individual for the educational program; (3) if the alternative is a diet program, the program is not required to pay for the cost of food but must pay any participation or membership fees; and (4) if an individual's personal physician states that the standard is not medically appropriate, the program must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness.
   - If the reasonable alternative standard is an activity-only program, the alternative also must satisfy the applicable activity-only program rules.
   - If the reasonable alternative standard is an outcome-based program, the alternative must satisfy the applicable outcome-based program rules and, if both the initial standard and the alternative standard are outcome-based programs, the alternative cannot be a requirement to meet a different level of the same standard without additional time to comply and the individual must be given the opportunity to comply with recommendations of his or her physician.
5. The program must disclose in all materials describing the terms of the program the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of a waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that the recommendations of an individual's personal physician will be accommodated, subject to the following:
   - If program materials merely mention that such a program is available, without describing its terms, this disclosure is not required. For example, a summary of benefits and coverage that notes that cost sharing may vary based on participation in a diabetes wellness program, without describing the standards of the program, would not trigger the disclosure. In contrast, a plan disclosure that references a premium differential based on tobacco use is a disclosure describing the terms of a health-contingent wellness program and, therefore, must include this disclosure.
   - The following model language can be used to satisfy the disclosure requirement: "Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and, if you wish, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status."

ACA Requirements

In addition to codifying HIPAA's non-discrimination requirements as described above, the ACA included a number of other provisions that either explicitly address wellness or impact wellness programs that are themselves group health plans or that are part of a group health plan. This section of the article focuses on the ACA's market reform provisions and the impact of certain wellness program rewards on employer mandate determinations under the ACA.

ACA's Market Reform Provisions

If a wellness program is itself a group health plan, or is part of a group health plan, then it must comply with the ACA's market reform provisions, such as the prohibition on lifetime and annual limits on the dollar value of essential health benefits, 100% first-dollar coverage of preventive health services, the adult child coverage mandate, and the prohibition on rescissions, among others. Technically, a wellness program may be able to avoid some or all of these requirements if it is considered a grandfathered health plan under the ACA, if it is a retiree-only plan, or if it provides only excepted benefits, such as limited-scope dental or vision benefits. However, practically speaking, most wellness programs do not qualify for one of these exceptions.

A wellness program that is structured as a stand-alone group health plan and is subject to the ACA's market reform provisions will likely

> Under the ACA's employer mandate, applicable large employers may be subject to a penalty tax for failing to offer full-time employees (and their dependent children) minimum essential coverage that is affordable and provides minimum value.

have a hard time complying with those provisions because wellness programs do not typically provide unlimited essential health benefits or 100% coverage of preventive care, for example. As a result, an employer may be required to structure its wellness program as part of its major medical plan to rely on the medical plan's compliance with the ACA's market reform provisions. Failing to comply with these provisions can result in a $100 per day excise tax liability per violation per person, as well as Department of Labor enforcement actions and participant lawsuits.

Impact of Wellness Program Rewards on ACA's Employer Mandate Determinations

Under the ACA's employer mandate, applicable large employers may be subject to a penalty tax for failing to offer full-time employees (and their dependent children) minimum essential coverage that is affordable and provides minimum value. Wellness program incentives (which can be in the form of rewards, discounts, or penalties) may directly impact the cost of coverage (e.g., by lowering or raising the employee's required contribution rate) and/or the value of coverage (e.g., by lowering or raising the deductible or other cost-sharing amounts).

However, for purposes of the affordability and minimum value determinations under the ACA's employer mandate, only incentives relating to tobacco use will be taken into account. Incentives that affect deductibles, co-payments, or other cost sharing are treated as earned in determining a plan's minimum value percentage to the extent the incentives relate to tobacco use. Similarly, incentives that affect the employee's contribution rate are treated as earned in determining a plan's affordability to the extent the incentives relate to tobacco use. Wellness program incentives that do not relate to tobacco use are treated as not earned for purposes of these affordability and minimum value determinations.

The following are examples of how wellness program incentives impact affordability and minimum value determinations under the ACA's employer mandate:

Example 1. An employer sponsors a wellness program as part of its major medical plan that has a $2,000 in-network individual deductible. Employees who do not use tobacco receive a $500 reduction in that deductible, and employees who complete an HRA receive another $100 reduction in that deductible. The plan's minimum value percentage would be determined using $1,500 as the in-network individual deductible amount because the $500 tobacco-related discount is treated as earned, but the $100 HRA-related discount is treated as unearned.

Example 2. An employer sponsors a wellness program as part of its major medical plan for which the employee-only contribution rate is $250 per month. Employees who do not use tobacco receive a $50 reduction in their monthly contribution rate, and employees who complete an HRA receive another $25 reduction in their monthly contribution rate. The plan's affordability would be determined using $200 as the monthly employee-only contribution rate because the $50 tobacco-related discount is treated as earned, but the $25 HRA-related discount is treated as unearned.

Other ACA Requirements

W-2 Reporting

Employers filing at least 250 W-2 forms must report in Box 12, Code DD, the aggregate cost of applicable employer-sponsored coverage. The cost of coverage provided under a wellness program must be included in the aggregate reportable cost only if the wellness program is a group health plan and the employer charges a COBRA premium for that coverage. If an employer does not charge a COBRA premium for that coverage, the employer can, but is not required to, include the cost of wellness program coverage in the amount reported on the W-2.

Patient-Centered Outcomes Research Institute (PCORI) Fees

For plan or policy years ending before October 1, 2019, employers sponsoring self-insured group health plans must pay PCORI fees, which are intended to support clinical effectiveness research. PCORI fees apply to a wellness program only if the program provides significant benefits in the nature of medical care or treatment. A wellness program that does not provide such significant benefits is not subject to PCORI fees. Although applicable guidance does not specify when a wellness program benefit would be considered "significant," typical wellness programs that include an HRA, biometric screening, or limited health coaching likely would not be viewed as providing significant benefits in the nature of medical care or treatment, and therefore would not be subject to the PCORI fees.

Reinsurance Contributions

From 2014 through 2016, each state that operates a health insurance exchange was required to establish a temporary reinsurance program for the non-grandfathered plans individual market, to which health insurers and group health plans were required to contribute. However, reinsurance contributions were not required for a wellness program if the program did not provide major medical coverage. Typical wellness programs that include an HRA, biometric screening, or limited health coaching do not rise to the level of major medical coverage and, therefore, were not subject to the reinsurance contribution requirements.

GINA Requirements

Both of GINA's two main titles also can impact wellness program design.

Title I Requirements (Genetic Information Non-discrimination in Health Coverage)

A wellness program must comply with Title I of GINA if it is itself a group health plan or is part of a group health plan. Title I prohibits group health plans from (1) adjusting group premium or contribution rates on the basis of genetic information; (2) requesting or requiring an individual or an individual's family members to undergo genetic testing; and (3) requesting, requiring, or purchasing genetic information for underwriting purposes or prior to or in connection with enrollment.[2]

For these purposes:

- Genetic information, with respect to an individual, means information about (1) the individual's genetic tests, (2) the genetic tests of the individual's family members, and (3) the manifestation of a disease or disorder in the individual's family member (i.e., family medical history). Such information also includes an individual's request for or receipt of genetic services but does not include information about an individual's sex or age.
- A genetic test is a specialized test which analyzes human DNA, RNA, chromosomes, proteins, or metabolites, and detects genotypes, mutations, and chromosomal changes, but does not include common biometric tests such as body mass index testing, blood pressure screening, and cholesterol screening.
- The manifestation of a disease or disorder means that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a healthcare professional with appropriate training and expertise in the field of medicine involved. A disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.
- Underwriting purposes, with respect to a group health plan, means:
  - Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing an HRA or participating in a wellness program)
  - The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing an HRA or participating in a wellness program)
  - The application of any pre-existing condition exclusion under the plan or coverage
  - Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits
- Genetic information is collected prior to or in connection with enrollment when it is collected prior to the individual's effective date of coverage under the plan.
- A family member includes not only relatives by consanguinity (i.e., having a common biological ancestor), but also by affinity (i.e., by adoption or marriage), even though the employee and spouse or an adopted child are not biologically related to one another.

Applying these definitions, it appears that the following types of wellness programs involve the collection of genetic information as defined under Title I of GINA:

- A wellness program using an HRA for employees that includes family medical history questions
- A wellness program requiring a covered spouse to complete an HRA that includes questions where the answer will provide information about the manifestation of a disease or disorder in the spouse
- A wellness program requiring a covered spouse to complete a biometric screening, the results of which provide information about the manifestation of a disease or disorder in the spouse

Because GINA prohibits the collection of genetic information for underwriting purposes, which includes changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing an HRA or participating in a wellness program, the types of wellness programs highlighted above may give rise to compliance issues under Title I of GINA.

We discuss below approaches that can be taken to mitigate the GINA Title I risk related to these common wellness program designs. Note, however, that no request or acquisition of genetic information about any individual is permitted prior to or in connection with the individual's enrollment under a group health plan.

Title II Requirements (Genetic Information Non-discrimination in Employment)

Title II of GINA applies to employers rather than to group health plans. As a result, an employer must consider Title II's requirements even if its wellness program is not itself a group health plan or part of a group health plan. Title II prohibits employers from discriminating against their employees on the basis of genetic information and, subject to limited exceptions, prohibits employers from requesting, requiring, or purchasing genetic information with respect to an employee or a family member of the employee.[3]

The Equal Employment Opportunity Commission (EEOC) issued final regulations addressing compliance with Title II of GINA on November 9, 2010, and issued updated final regulations on May 17, 2016 addressing the limited circumstances under which an employer may offer an inducement to an employee for the employee's spouse to provide information about the spouse's manifestation of disease or disorder in connection with an employer-sponsored wellness program.[4] The 2016 final regulations became effective on July 18, 2016. The 2010 and 2016 final regulations (GINA Wellness Program Regulations) provided much needed clarity regarding the extent to which inducements could be used as part of a wellness program that includes genetic information. However, the U.S. District Court for the District of Columbia created renewed uncertainty for employers regarding compliance with Title II of GINA in December 2017 by vacating the incentive provisions of the GINA Wellness Program Regulations effective as of January 1, 2019.[5] The EEOC issued updated final rules formally eliminating the incentive provisions effective as of January 1, 2019.[6] In the absence of further EEOC guidance, employers are once again in the uncomfortable position of not knowing with certainty whether and to what extent they may offer an inducement to an employee for the employee's spouse to provide information about the spouse's manifestation of disease or disorder in connection with an employer-sponsored wellness program.

The following describes the provisions of the GINA Wellness Program Regulations and the impact of the *AARP v. EEOC* decision on compliance with Title II of GINA pending issuance of new EEOC guidance.

2. 29 U.S.C. § 1182(b)(3), (c), (d); 42 U.S.C. § 300gg-1(b)(3), (c), (d); 26 U.S.C. § 9802(b)(3), (c), (d).

3. 42 U.S.C.S. §§ 2000ff to 2000ff-11; 29 C.F.R. §§ 1635.1 to 1635.12. 4. 81 Fed. Reg. 31,143 (May 17, 2016) (codified at 29 C.F.R. § 1635.8). 5. AARP v. EEOC, 292 F. Supp. 3d 238 (D.D.C. 2017), modified by 2018 U.S. Dist. LEXIS 27317 (D.D.C. 2018). 6. 83 Fed. Reg. 65,296 (Dec. 20, 2018) (removing and reserving 29 C.F.R. § 1635.8(b)(2)(iii)).

Acquisition of Genetic Information

Under the GINA Wellness Program Regulations, an employer can request, require, or purchase genetic information about an employee or a family member of the employee if the employer offers health or genetic services, including as part of a voluntary wellness program, and all of the following conditions are satisfied:

- **Reasonable design**. The program services, including any acquisition of genetic information that is part of those services, are reasonably designed to promote health or prevent disease. A program satisfies this requirement if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and is not (1) overly burdensome (e.g., an overly long participation requirement), (2) a subterfuge for violating Title II of GINA or other laws prohibiting employment discrimination, or (3) highly suspect in the method chosen to promote health or prevent disease.
- **Voluntary provision of information**. The provision of genetic information by the individual is voluntary, meaning the employer cannot require the individual to provide genetic information, nor can it penalize those individuals who choose not to provide it.
- **Prior authorization**. The individual provides prior knowing, voluntary, and written authorization, using an authorization form that (1) is written in a manner that is reasonably likely to be understood by the individual, (2) describes the type of genetic information that will be obtained and the general purposes for which it will be used, and (3) describes the restrictions on disclosure of genetic information.
- **Disclosure limitation**. Individually identifiable genetic information is provided only to the individual (or family member if the family member is receiving genetic services) and the licensed healthcare professionals or board-certified genetic counselors involved in providing such services, and is not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace.
- **Use limitation**. Any individually identifiable genetic information is only available for purposes of such services and is not disclosed to the employer except in aggregate terms that do not disclose the identity of specific individuals.[7]

Inducements for Provision of Genetic Information

Under the GINA Wellness Program Regulations, an employer may not offer any inducement (whether financial or in-kind and whether in the form of a reward or penalty) for individuals to provide genetic information. However, an employer may offer inducements for completion of an HRA that includes questions about family medical history or other genetic information, provided the employer makes it clear that the inducement will be made available whether or not the participant answers questions regarding genetic information.

The vacated provisions of the GINA Wellness Program Regulations had provided that an employer could offer inducements for an employee's spouse to provide information about the spouse's manifestation of disease or disorder (but not any other genetic information, including the results of the spouse's genetic tests) as part of an HRA (in the form of a questionnaire or a medical examination or both), subject to certain limitations. These limitations were intended to ensure that participation remained voluntary, without the inducement becoming unduly coercive. The District Court for the District of Columbia vacated these provisions, finding that the EEOC failed to provide support for the specified limitations, rendering its interpretation of "voluntary" arbitrary and capricious.[8]

One of the restrictions for voluntary programs in the vacated provisions of the GINA Wellness Program Regulations was that no inducements were permitted to provide genetic information (including information about the manifestation of a disease or disorder) regarding an employee's child (even an adult or adopted child). Employers considering inducements should be mindful of the EEOC's view regarding this issue.

An employer may offer financial inducements to encourage individuals who have voluntarily provided genetic information (e.g., family medical history) that indicates that they are at increased risk of acquiring a health condition in the future to participate in disease management programs or other programs that promote healthy lifestyles and/or to meet particular health goals as part of a health or genetic service. However, to comply with the GINA Wellness Program Regulations, these programs must also be offered to individuals with current health conditions and/or to individuals whose lifestyle choices put them at increased risk of developing a condition.

In no case may an employer condition participation in a wellness program on, or provide any inducement in exchange for, an agreement permitting the sale, exchange, sharing, transfer, or other disclosure of genetic information (other than transfers to healthcare professionals or genetic counselors providing genetic services or to the individual or family member). In addition, an employer cannot deny access to health insurance or any package of health insurance benefits to an employee or eligible family member, or retaliate against an employee, due to a spouse's refusal to provide information about his or her manifestation of disease or disorder to a wellness program.

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7. 29 C.F.R. § 1635.8(b)(2). 8. *See* AARP v. EEOC, 267 F. Supp. 3d 14, 36–37 (D.D.C. 2017).

Wellness Program Designs to Mitigate GINA Risk

To avoid GINA non-compliance, an employer can consider the following wellness program designs, particularly if it intends to include spouses in an HRA or biometric screening component of the program:

No genetic information program. Don't request or require any genetic information (including family medical history) from participants.

Programs involving genetic information—GINA Title I compliance. For a wellness program that is a group health plan or is part of a group health plan and thus is subject to Title I of GINA, no inducement can be offered for the collection of genetic information. The following wellness program designs are options to consider that comply with Title I of GINA:

- Make the provision of any genetic information purely voluntary, and do not impose a penalty or prevent or inhibit participation based on a refusal to provide genetic information.
- Either (1) don't provide an inducement to the employee (and don't vary the level of inducement provided to the employee) based on whether the employee completes an HRA with family medical history questions or (2) provide an inducement only for completion of that portion of an HRA that does not cover family medical history or otherwise request genetic information, and make completion of the genetic information questions optional.
  - If an inducement is offered for completing an HRA that contains genetic information questions, bifurcate the HRA and make sure it's clear that any medical history questions are entirely optional such that the inducement that's provided is not dependent on whether those medical history questions are answered or not.

Programs involving genetic information—GINA Title II compliance. A wellness program that is not a group health plan and is not part of a group health plan is only subject to Title II of GINA. Based on the developments described above and pending the issuance of further EEOC guidance, it is once again unclear whether and to what extent employers may offer an inducement to an employee for the employee's spouse to provide information about the spouse's manifestation of disease or disorder in connection with an employer-sponsored wellness program. As a result, until further EEOC guidance is issued, the only wellness program designs that will definitively comply with Title II of GINA are ones that do not offer any inducement for the collection of genetic information, similar to the wellness program designs described with respect to GINA Title I compliance above. These types of wellness programs can still include biometric screening and HRA features that employees and spouses are encouraged to complete, but no rewards or penalties would be associated with whether the employee or spouse completes an HRA or biometric screening involving genetic information. Employers that provide only modest inducements in connection with wellness programs involving genetic information will be subject to incremental risk under the GINA Wellness Program Regulations, but may still be compliant with Title II of GINA.

ADA Requirements

Title I of the ADA has two primary requirements that an employer should consider when designing its wellness program, whether or not the wellness program is itself a group health plan or part of a group health plan: (1) the program must not be discriminatory with respect to disability, and (2) medical examinations and inquiries generally must be voluntary.[9]

The EEOC issued final regulations on wellness programs under the ADA on May 17, 2016 (ADA Wellness Program Regulations).[10] The ADA Wellness Program Regulations became effective on July 18, 2016 and provided much needed clarity regarding how wellness programs should be designed to ensure compliance with the ADA. However, the District Court for the District of Columbia created renewed uncertainty for employers regarding compliance with the ADA in December 2017 by vacating the incentive provisions of the ADA Wellness Program Regulations effective as of January 1, 2019.[11] The EEOC issued updated final rules formally eliminating the incentive provisions effective as of January 1, 2019.[12]

The following describes the provisions of the ADA Wellness Program Regulations and the impact of the *AARP v. EEOC* decision on compliance with the ADA pending the issuance of further EEOC guidance.

Prohibition of Discrimination against Disabled Individuals

An employer cannot discriminate against a qualified employee on the basis of disability with regard to the terms, conditions, and privileges of employment. When designing and administering a wellness program, which is a privilege of employment, an employer should ensure that qualified employees with disabilities will have equal access to the program's benefits and will not have to satisfy greater obligations to obtain equal benefits under the program.

Reasonable accommodations must be provided, absent undue hardship, to enable employees with disabilities to earn whatever financial incentive an employer offers as part of its wellness program. Providing a reasonable alternative standard and notice to employees of the availability of a reasonable alternative under HIPAA and the ACA as part of a health-contingent program would likely fulfill an employer's obligation to provide a reasonable accommodation under the ADA. However, reasonable accommodation under the ADA is also required for a participation-only program even though HIPAA does not require participation-only programs to offer a reasonable alternative standard. The ADA Wellness Program Regulations provide the following examples:

- An employer that offers employees a financial incentive to attend a nutrition class, regardless of whether they reach a healthy weight as a result, would have to provide a sign language interpreter so that an employee who is deaf and who needs an interpreter to understand the information communicated in the class could earn the incentive, as long as providing the interpreter would not result in undue hardship to the employer.
- An employer would, absent undue hardship, have to provide written materials that are part of a wellness program in an alternate format, such as in large print or on computer disk, for someone with a vision impairment.
- An employer that offers a reward for completing a biometric screening that includes a blood draw would, absent undue hardship, have to provide an alternative test (or certification requirement) so that an employee with a disability that makes drawing blood dangerous can participate and earn the incentive.

Medical Examinations and Inquiries Must Be Voluntary

The ADA generally prohibits an employer from requiring medical examinations or making medical inquiries, unless such examination or inquiry is job-related and consistent with business necessity or is voluntary and part of an employee health program.

The ADA Wellness Program Regulations clarified that a program that simply promotes a healthier lifestyle but does not ask any disability-related questions or require medical examinations (e.g., a smoking cessation program that is available to anyone who smokes and only asks participants to disclose how much they smoke) is not subject to these ADA prohibitions. However, a wellness program that includes a biometric screening and/or disability-related inquiries must be designed to comply with the ADA Wellness Program Regulations' voluntary health program exception described below to comply with the ADA (even if it is a participation-only program).

Voluntary Employee Health Program Exception

Under the ADA Wellness Program Regulations, an employer may conduct voluntary medical examinations and inquiries as part of an employee health program (such as medical screening for high blood pressure, weight control, and cancer detection), provided that:

- Participation in the program is voluntary (as described further below)
- Information obtained is maintained according to the confidentiality requirements of the ADA[13]
- This information is not used to discriminate against an employee

9. 42 U.S.C.S. § 12112(a), (d). **10.** 81 Fed. Reg. 31126 (May 17, 2016) (codified at 29 C.F.R. § 1630.14(d)). **11.** AARP v. EEOC, 292 F. Supp. 3d 238, modified by 2018 U.S. Dist. LEXIS 27317. **12.** 83 Fed. Reg. 65296 (Dec. 20, 2018) (removing and reserving 29 C.F.R. § 1630.14(d)(3)). **13.** Including under 29 C.F.R. § 1630.14(d)(4).

Such an employee health program (which may be offered in connection with a wellness program) must be reasonably designed to promote health or prevent disease, taking into account all the relevant facts and circumstances. This rule is similar to the standard for health-contingent wellness programs and the reasonable design criterion under GINA described above and generally means that the program:

- Has a reasonable chance of improving the health of, or preventing disease in, participating employees
- Is not overly burdensome
- Is not a subterfuge for violating the ADA or other laws prohibiting employment discrimination
- Is not highly suspect in the method chosen to promote health or prevent disease

The ADA Wellness Program Regulations provide examples of programs that would and would not meet this requirement. Specifically, collecting medical information through an HRA without providing employees follow-up information or advice, such as providing feedback about risk factors or using aggregate information to design programs or treat any specific conditions, would not be reasonably designed to promote health. A program also is not reasonably designed if it exists mainly to shift costs from the employer to targeted employees based on their health.

However, conducting an HRA and/or a biometric screening of employees for the purpose of alerting them to health risks of which they may have been unaware would meet this requirement, as would the use of aggregate information from employee HRAs by an employer to design and offer health programs aimed at specific conditions that are prevalent in the workplace. An employer might conclude from aggregate information, for example, that a significant number of its employees have diabetes or high blood pressure and might design specific programs that would enable employees to treat or manage these conditions.

Under the ADA Wellness Program Regulations, participation in a wellness program (or other employee health program) is considered voluntary for this purpose if the employer:

- Does not require employees to participate
- Does not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation or limit the extent of benefits (except pursuant to allowed incentives) for employees who do not participate
- Does not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees
- Provides employees with a notice written in a manner that is reasonably likely to be understood that describes the type of medical information that will be obtained and the specific purposes for which it will be used along with the applicable restrictions on disclosure, the parties with whom it will be shared, and the methods to ensure that medical information is not improperly disclosed[14]

Participation Incentives

The extent to which an employer may provide incentives for wellness program participation without jeopardizing its voluntary status is uncertain. The vacated provisions of the ADA Wellness Program Regulations had provided that an employer could offer limited incentives (whether financial or in-kind) to promote an employee's participation in a wellness program that includes disability-related inquiries or medical examinations. The incentive limitations were intended to ensure that participation remained voluntary, without the inducement becoming unduly coercive. The District Court for the District of Columbia vacated the incentive limitations, finding that the EEOC failed to provide support for the specified limitations, rendering its interpretation of "voluntary" arbitrary and capricious.[15] Absent this rule, employers that provide only modest inducements in connection with wellness programs involving disability-related inquiries or medical examinations will be subject to incremental risk under the ADA Wellness Program Regulations, but may still be compliant with the ADA.

Other Design Considerations

An employer cannot require an employee to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted by the ADA Wellness Program Regulations to carry out specific activities related to the wellness program), or to waive any confidentiality protections in this part as a condition for participating in a wellness program or for earning any incentive the employer offers in connection with such a program.

14. See the EEOC website for a sample notice, https://www.eeoc.gov/laws/regulations/ada-wellness-notice.cfm. **15.** *See* AARP v. EEOC, 267 F. Supp. 3d at 36–37.

Now that the ADA and 2016 GINA Wellness Program Regulations have been vacated, it would not be surprising to see additional EEOC enforcement actions.

Medical information obtained by wellness programs subject to the ADA Wellness Program Regulations may only be disclosed to employers in aggregate form. Where a wellness program is part of a group health plan and is required to comply with HIPAA, its obligation to comply with this requirement generally may be satisfied through the group health plan's compliance with the HIPAA Privacy Rule.

Note that a smoking cessation program that merely asks employees whether they use tobacco (or whether they ceased using tobacco upon completion of the program) is not an employee health program that includes disability-related inquiries or medical examinations. As such, the vacated incentive limitations in the ADA Wellness Program Regulations would not have applied to such a program. Rather, only the HIPAA/ACA non-discrimination cap would apply, so an employer would be permitted to offer incentives as high as 50% of the cost of employee coverage for such a program. However, a tobacco-related program that tests for the presence of nicotine or tobacco would be an employee health program that includes disability-related inquiries or medical examinations. As a result, absent the vacated incentive limitations, employers that provide only modest inducements in connection with these types of tobacco-related programs will be subject to incremental risk under the ADA Wellness Program Regulations, but may still comply with the ADA.

Bona Fide Benefit Plan Safe Harbor and ADA Compliance

The ADA also includes a safe harbor exception to these ADA requirements that permits insurers or other benefit plan administrators (including employers) to establish or administer benefit plans that are based on underwriting risks. The U.S. Court of Appeals for the Eleventh Circuit affirmed a district court's finding,[16] which held that a wellness program that imposed a penalty for nonparticipation was part of the employer's bona fide benefit plan and thus able to take advantage of this safe harbor. However, the EEOC disagrees with this decision and does not believe that the ADA's safe harbor provision is applicable to an employer's decision to offer rewards or impose penalties in connection with wellness programs that include disability-related inquiries or medical examinations. Rather, the EEOC's position is that the voluntary employee benefit plan exception discussed above[17] is the ADA's clear safe harbor for wellness programs and that reading the insurance safe harbor as exempting these programs from the ADA prohibitions would render that statute superfluous. In light of the EEOC's continued opposition to the outcome in *Seff* and similar cases, an employer that implements a wellness program in reliance on the bona fide benefit plan safe harbor will need to weigh the risks of an EEOC challenge. The EEOC has been active in this area, as noted in the following section.

EEOC Enforcement Actions

In the fall of 2014, the EEOC filed three lawsuits against three employers, alleging that their wellness programs violated the ADA and GINA:

- ***EEOC v. Orion Energy Systems.*** Employees who declined to participate in the employer's wellness program, which included mandatory medical exams, were required to pay full premium for group health plan coverage (otherwise 100% employer-paid) and one employee was dismissed after complaining about the program.[18]
- ***EEOC v. Flambeau, Inc.*** Employees who declined to participate in the employer's wellness program were required to pay full premium for group health plan coverage (otherwise 75% employer-paid) and were subject to unspecified disciplinary action. The district court granted the employer's motion for summary judgment, finding the program was permitted under the bona fide benefit plan safe harbor discussed above.[19]
- ***EEOC v. Honeywell Int'l Inc.*** The EEOC sought a preliminary injunction to enjoin the employer from imposing certain financial penalties on employees who declined to participate in its wellness program. The court denied the motion for lack of irreparable harm.[20]

Although the first two cases involved severe penalties equal to the full cost of coverage and even termination of employment, the third case involved a more typical design that complies with HIPAA's non-discrimination requirements. These enforcement actions alarmed many employers that had been careful to design wellness programs in compliance with HIPAA's non-discrimination requirements. Now that the ADA and 2016 GINA Wellness Program Regulations have been vacated, it would not be surprising to see additional EEOC enforcement actions.

AARP v. EEOC

In August 2016, AARP filed a lawsuit in the U.S. District Court for the District of Columbia challenging the ADA Wellness Program Regulations under the Administrative Procedure Act. AARP claimed

16. Seff v. Broward County, 778 F. Supp. 2d 1370 (S.D. Fla. 2011), *aff'd* 691 F.3d 1221 (11th Cir. 2012). **17.** Codified at 42 U.S.C.S. § 12112(a), (d)(4)(B). **18.** 145 F. Supp. 3d 841 (E.D. Wis. 2015). **19.** 131 F. Supp. 3d 849 (W.D. Wis. 2015). **20.** 2014 U.S. Dist. LEXIS 157945 (D. Minn. Nov. 6, 2014).

that permitting incentives of up to 30% of the cost of self-only coverage is inconsistent with the voluntary requirements of the ADA, and that the EEOC failed to adequately explain and support its adoption of the 30% incentive level. In August 2017, the court ruled that the EEOC had not provided a reasoned explanation for its interpretation of the voluntary requirement, and that the ADA Wellness Program Regulations were therefore arbitrary and capricious. In that ruling, the court remanded the ADA Wellness Program Regulations back to the EEOC for reconsideration. However, in an effort to avoid widespread disruption and confusion among employers sponsoring wellness programs and their employees, the court did not vacate the ADA Wellness Program Regulations at that time.

AARP then asked the court to reconsider its decision not to vacate the ADA Wellness Program Regulations, and the EEOC provided a status report to the court indicating that new proposed regulations would not be issued until August 2018, would not be finalized until October 2019, and would not be effective until 2021. In response to the AARP's request for reconsideration and in light of the EEOC's anticipated timeline, the court issued another ruling in late December 2017 vacating the ADA Wellness Program Regulations effective January 1, 2019.

Under the court's most recent ruling in *AARP v. EEOC*, the ADA Wellness Program Regulations, summarized above, remained effective for 2018 but became null and void beginning on January 1, 2019. In the absence of further EEOC guidance, employers are once again in the uncomfortable position of not knowing with certainty whether and to what extent they can use incentives as part of a wellness program that involves medical examinations and disability-related inquiries.

Coextensive Statutory Regimes

Federal agencies have consistently indicated that compliance with one set of legal requirements, such as the HIPAA non-discrimination requirements described above, does not guarantee that a wellness program complies with other legal requirements, such as the ADA's voluntariness requirement. For example, even if a program and associated reward comply with HIPAA and GINA, the program and associated reward do not automatically comply with the ADA as well. Rather, the program and associated reward must comply with all applicable rulemaking.

Other Legal Requirements

In addition to the HIPAA non-discrimination, ACA, GINA, and ADA legal requirements discussed above, a wellness program that is itself a group health plan or part of a group health plan must comply with other legal requirements, such as ERISA, COBRA, and HIPAA privacy and security requirements. The need to comply with these additional legal requirements may be another reason for an employer to structure its wellness program as part of its major medical plan, which should already have compliance mechanisms in place for these requirements. If a wellness program provides a reward to incentivize participation, the employer also will need to determine the tax treatment of that reward under the Code.

ERISA

A wellness program that is itself a group health plan or part of a group health plan must comply with ERISA. Some of the primary compliance obligations under ERISA include having a written plan document, distributing a summary plan description and summaries of material modifications to participants, filing a Form 5500 if there are more than 100 participants in the plan, and following specific claims and appeals procedure requirements.

A wellness program that is part of a group health plan can simply be folded into the health plan's compliance with these requirements. A stand-alone wellness program will need to determine how to comply with these requirements in its own right.

COBRA

COBRA continuation coverage must be offered as part of a wellness program that is itself a group health plan or part of a group health plan. If the wellness program is a stand-alone plan, the COBRA election notice provided to qualified beneficiaries at the time of a COBRA qualifying event should list the wellness program as coverage that can be continued under COBRA, together with any COBRA premium the employer decides to charge for such coverage. An actuary may need to be engaged to determine the fair market value of coverage under the program on which to base any COBRA premium charged.

If the wellness program is part of the employer's group health plan, the COBRA election notice does not need to list the program separately. Rather, a COBRA qualified beneficiary's election of COBRA coverage with respect to the group health plan should automatically provide continued coverage under the wellness program as well.

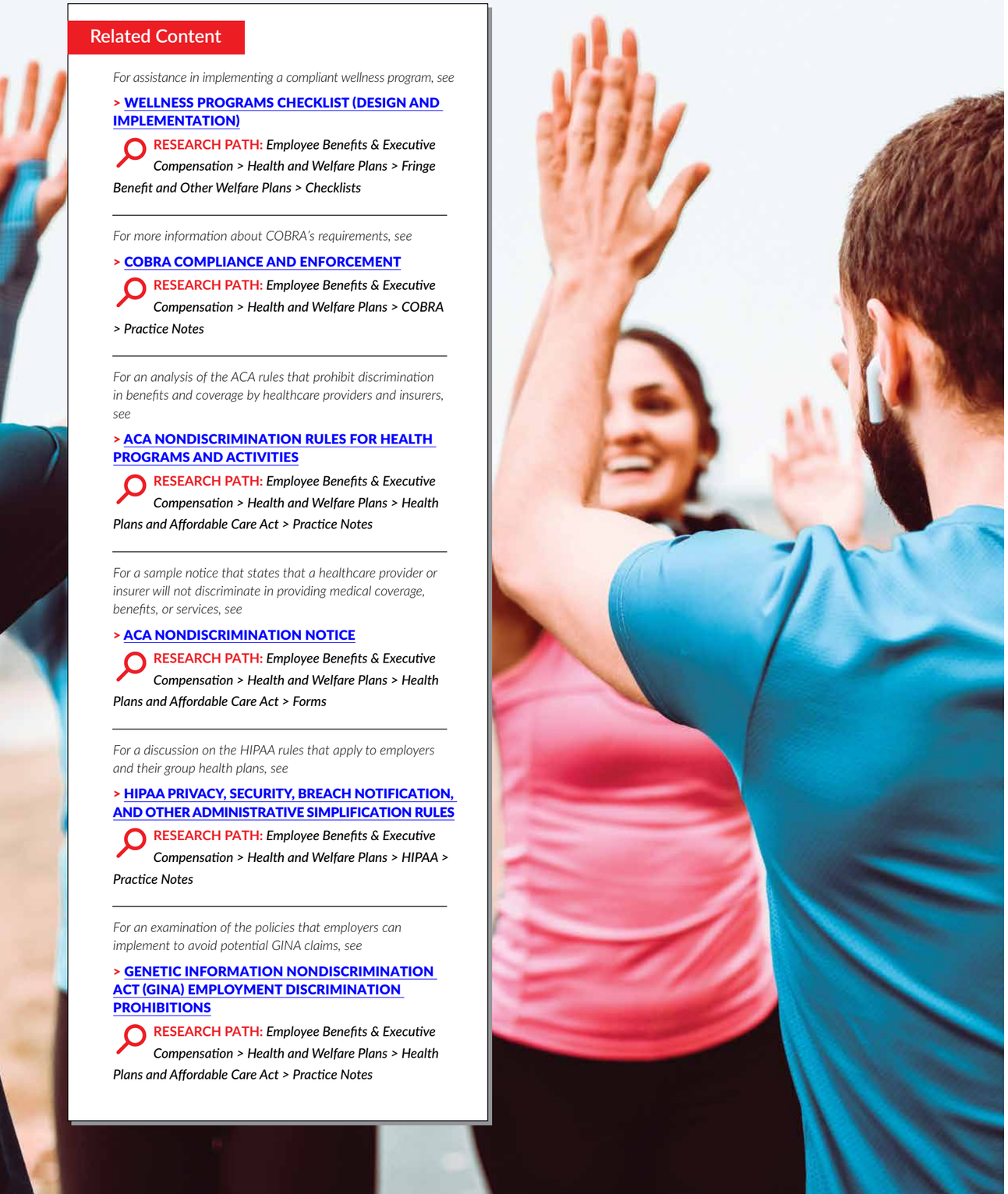
A general rule under COBRA is that a COBRA qualified beneficiary should be treated the same as a similarly situated active employee covered under the plan. However, identical treatment for wellness program purposes may not be required in certain circumstances:

- If the wellness program includes an on-site biometric screening, the on-site location of the screening probably does not need to be offered to COBRA qualified beneficiaries, as long as they could receive the same screening at another, reasonably accessible location.
- If the wellness program provides a reward in the form of reduced employee contribution rates, that reward probably does not need to be offered in COBRA to reduce the required COBRA premium because an employer can charge up to 102% of a plan's full cost rate in COBRA (in other words, a COBRA qualified beneficiary does not have to be treated the same as a similarly situated active employee when it comes to the cost that's charged for coverage).
- Similarly, if the wellness program provides a reward in the form of health savings account (HSA) contributions, cash, cash equivalent, or other non-group health plan–related form, the reward probably does not need to be offered in COBRA. HSAs are not typically ERISA plans and thus not subject to COBRA, and other non-group health plan–related rewards also are not subject to COBRA.
- If the wellness program provides a reward in the form of a health reimbursement arrangement or health flexible spending account contribution, or reduced cost sharing under the medical plan (i.e., lower deductible, co-payment, or coinsurance), the reward probably does need to be offered in COBRA. Health reimbursement arrangements and health flexible spending accounts are group health plans subject to COBRA, and the cost-sharing features under a medical plan should be consistent between similarly situated active employees and COBRA qualified beneficiaries.

HIPAA Privacy and Security

A wellness program that is itself a group health plan or part of a group health plan must comply with HIPAA's privacy and security requirements as a covered entity under HIPAA. Some of the primary compliance obligations under HIPAA's privacy and security rules include having business associate agreements in place with the third-party service providers, providing participants with a privacy notice, maintaining and following a policies and procedures document, and notifying individuals of breaches of unsecured protected health information.

A wellness program that is part of a group health plan can simply be folded into and included in the group health plan's compliance with these requirements. A stand-alone wellness program will need to determine how it will comply with these requirements in its own right.



Related Content

For assistance in implementing a compliant wellness program, see

> **WELLNESS PROGRAMS CHECKLIST (DESIGN AND IMPLEMENTATION)**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Fringe Benefit and Other Welfare Plans > Checklists*

For more information about COBRA's requirements, see

> **COBRA COMPLIANCE AND ENFORCEMENT**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > COBRA > Practice Notes*

For an analysis of the ACA rules that prohibit discrimination in benefits and coverage by healthcare providers and insurers, see

> **ACA NONDISCRIMINATION RULES FOR HEALTH PROGRAMS AND ACTIVITIES**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Practice Notes*

For a sample notice that states that a healthcare provider or insurer will not discriminate in providing medical coverage, benefits, or services, see

> **ACA NONDISCRIMINATION NOTICE**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Forms*

For a discussion on the HIPAA rules that apply to employers and their group health plans, see

> **HIPAA PRIVACY, SECURITY, BREACH NOTIFICATION, AND OTHER ADMINISTRATIVE SIMPLIFICATION RULES**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > HIPAA > Practice Notes*

For an examination of the policies that employers can implement to avoid potential GINA claims, see

> **GENETIC INFORMATION NONDISCRIMINATION ACT (GINA) EMPLOYMENT DISCRIMINATION PROHIBITIONS**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Practice Notes*

The Code

Generally, anything of value provided from an employer to an employee, including a wellness program incentive, is included in the employee's taxable income. However, in some cases an employer may be able to design wellness program rewards that are not taxable to the employee. According to the Code:

- Cash and cash equivalents (e.g., gift cards) are always taxable to the employee, no matter the amount, including when provided directly to the employee's spouse.
- Items such as water bottles, T-shirts, etc. are generally considered non-taxable de minimis fringe benefits under Code section 132.
- Reduced employee medical plan contributions, deductibles, co-payments, and coinsurance amounts, as well as employer contributions to health reimbursement arrangements, health savings accounts, and health flexible spending accounts, are not taxable under Code sections 105 and 106.

Common Pitfalls

Some common pitfalls in designing and administering compliant wellness programs include the following:

- Failing to recognize when a wellness program is providing medical care and thus must comply with applicable group health plan requirements
- Offering a reward (or penalty) that exceeds the applicable limits under the HIPAA non-discrimination rules
- Requiring an individual to show that it is unreasonably difficult due to a medical condition or medically inadvisable to satisfy an outcome-based, health-contingent standard (such as non-tobacco user status) to access a reasonable alternative standard (as applicable under the HIPAA Wellness Program Regulations or the ADA)
- Requiring an individual to find and pay for his or her own educational program as a reasonable alternative standard
- Refusing to entertain the recommendation of an individual's physician in designing a reasonable alternative standard for the individual
- Failing to include in materials that describe the program notification that a reasonable alternative standard is available for health-contingent aspects of the program
- Structuring a wellness program that is a group health plan as a stand-alone plan without carefully planning how that stand-alone plan will comply with all applicable legal requirements
- Providing a reward or penalty based on whether an employee's spouse completes an HRA that includes medical history questions in a manner inconsistent with GINA
- Requiring a biometric screening as a condition of medical plan enrollment or imposing a penalty so large as to call into question the voluntary nature of the screening under the EEOC's ADA guidance
- Not having a summary plan description for a stand-alone wellness program that is a group health plan, or failing to include information in a medical plan's SPD about any wellness program that is part of that plan
- Failing to offer COBRA with respect to a wellness program that is itself a group health plan or is part of a group health plan
- Not having a HIPAA business associate agreement in place with third-party service providers for the wellness program when required if the program is itself a group health plan or is part of a group health plan
- Failing to tax a cash or other taxable reward that is not eligible for exclusion from employees' income under the Code

Importance of Periodic Wellness Program Reviews

Given the complexities and evolving landscape of legal compliance obligations and available guidance, it is extremely important to thoroughly analyze existing and proposed wellness program designs to ensure compliance with all applicable requirements and to mitigate against lawsuit and other enforcement action risks. L

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RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Fringe Benefit and Other Welfare Plans > Practice Notes*

Wellness Programs Design and Implementation Checklist

These guidelines will assist you in implementing a wellness program that complies with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Patient Protection and Affordable Care Act of 2010 (ACA), the Americans with Disabilities Act of 1990 (ADA), the Genetic Information Nondiscrimination Act of 2009 (GINA), the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code of 1986 (Code).

Program Structure

1. **Determine the group health plan status of the wellness program.** If the wellness program provides medical care, then it constitutes a group health plan that must comply with group health plan legal requirements and ongoing compliance obligations. A wellness program that simply promotes good health and a healthy lifestyle, does not provide medical care, and is not otherwise part of a group health plan has fewer compliance obligations.
2. **Decide whether to structure a wellness program that provides medical care as a stand-alone plan.** An employer that sponsors a wellness program that provides medical care must decide whether to structure the wellness program as a stand-alone group health plan, or as part of another group health plan sponsored by the employer, such as the employer's major medical plan. In counseling employers about this choice, note that it may be very challenging to ensure that a stand-alone wellness program complies with applicable group health plan mandates.
3. **Choose the reward/penalty structure.** To comply with the ACA's employer mandate, you must consider the regulatory percentage limitations, tax implications, and impact of incentives on affordability and minimum value determinations.

HIPAA Nondiscrimination Requirements

1. **Identify the participation-only aspects of the wellness program.** Wellness programs that only require that a participant participate in the program—and do not condition eligibility for a reward on the participant's ability to meet a particular health standard—entail fewer HIPAA nondiscrimination requirements.
2. **Offer the participation-only program to all similarly-situated individuals regardless of health status.** However, an employer may be able to treat different groups of similarly-situated individuals differently. In addition, an employer may treat a group of similarly-situated employees with an adverse health status more favorably than a group of similarly-situated employees who do not have that adverse health status (for example, a reward for completing a health coaching session may be offered only to a group of employees with high blood pressure).
3. **Identify health-contingent aspects of the wellness program.** HIPAA imposes more stringent nondiscrimination requirements on programs that condition eligibility for a reward on the participant's ability to meet a standard related to a health factor.
4. **Determine whether a health-contingent program is activity-only or outcome-based.** This determination impacts when and how a program must provide a reasonable alternative standard for a participant who cannot meet the primary standard.
5. **Ensure the health-contingent program meets the five applicable requirements.** The actions necessary to comply with each of these five requirements may vary depending on whether the health-contingent program is an activity-only program or an outcome-based program.

ACA Requirements

1. **Verify that the wellness program complies with the ACA's market reform provisions.** These requirements may be a good reason to structure a wellness program as part of a group health plan that already complies with the ACA's market reform provisions.
2. **Calculate the incentive impact on affordability and minimum value determinations under the ACA's employer mandate.** Incentives affecting major medical plan cost-sharing and/or contribution rates could impact the affordability and minimum value calculations.
3. **Confirm whether the wellness program impacts W-2 reporting, Patient-Centered Outcomes Research Institute fees, and/or reinsurance contributions.** Programs for which the employer does not charge a separate COBRA premium, which do not provide significant benefits in the nature of medical care or treatment, and which do not constitute major medical coverage should not be subject to these other ACA requirements.

GINA Requirements

1. **Title I: Ensure the wellness program does not collect genetic information for underwriting purposes.** Do not condition an incentive on the completion of a health risk assessment (HRA) that includes family medical history, spousal completion of an HRA with medical history questions, or spousal completion of a biometric screening.
2. **Title II: Verify that there is no discrimination on the basis of genetic information and that any acquisition of genetic information is voluntary.** These requirements apply whether or not the wellness program is itself a group health plan or part of a group health plan.

Jason Brocks LEXIS PRACTICE ADVISOR

Health Plan Network Provider Agreement Essentials

ADA Requirements

1. **Provide reasonable accommodations to enable employees with disabilities to earn wellness program incentives.** This requirement exists even for participation-only programs for which HIPAA's nondiscrimination requirements do not mandate a reasonable alternative standard.
2. **Ensure that any aspect of the wellness program involving a medical examination or disability-related inquiry is part of a voluntary employee health program.** The ADA generally prohibits an employer from requiring medical examinations or making medical inquiries, unless such examination or inquiry is job-related and consistent with business necessity or is voluntary and part of an employee health program.

Other Legal Requirements

1. **Verify compliance with ERISA.** Some of the primary compliance obligations under ERISA include having a written plan document, distributing a summary plan description and summaries of material modifications to participants, filing a Form 5500 if there are more than 100 participants in the plan, and following specific claims and appeals procedural requirements.
2. **Verify compliance with COBRA.** Wellness programs that themselves constitute group health plans or are a part of a group health plan must be offered to COBRA-qualified beneficiaries.
3. **Verify compliance with HIPAA privacy and security rules.** Some of the primary compliance obligations under HIPAA's privacy and security rules include having business associate agreements in place with third-party service providers, providing participants with a privacy notice, maintaining and following a policies and procedures document, and notifying individuals of breaches of unsecured protected health information.
4. **Verify compliance with the Code.** The nature of incentives and how they are structured will determine whether they constitute additional taxable income to employees.

*Checklist provided by **Emily D. Zimmer and Lynne S. Wakefield,** K&L Gates LLP*

RESEARCH PATH: *Employee Benefits and Executive Compensation > Health and Welfare Plans > Fringe Benefit and Other Welfare Plans > Checklists*

This article discusses provisions for agreements between health plans and doctors, dentists, and other healthcare professionals who provide healthcare services to plan members. It is intended as a guide for attorneys representing health plans who are asked to draft, review, or negotiate a provider agreement with providers who wish to participate in the health plan's provider network.

IT FOCUSES ON PROVIDER CONTRACTING FOR commercial plans and does not discuss provider agreements for Medicare Advantage or Medicaid managed care plans, which differ in substance from provider agreements for commercial plans. The article details provider network development and contracting, provider manuals, compensation, billing and payment, network participation, provider licensing and insurance, provider credentialing, maintenance of records, termination, and state contracting and filing requirements.

Provider Network Development and Contracting

Health plans are responsible for building their own networks of healthcare providers to provide healthcare services to plan members. Health plans market themselves in part based on the total number of providers in their networks. However, from a state regulator's and the health plan's perspective, the sheer number of providers in the network overall is only part of the story.

Under state health insurance laws, health plans must maintain adequate numbers of primary care and specialty providers within defined geographic areas to assure that covered members will have access to necessary care. Health plans spend tremendous resources to manage the adequacy of their healthcare provider networks to remain in compliance with state regulations.

The provider agreement is at the core of health plan provider networks. Health plans enter into provider agreements with providers who participate in their provider networks. Sometimes these agreements are with individual providers, while other agreements are with groups of providers such as medical practices, which employ and bill on behalf of the individual providers. Providers who enter into agreements with health plans are commonly called participating, in-network, or network providers. Unfortunately, the health plan-provider relationship tends to be adversarial in nature and in that context, health plans and their attorneys routinely reference provider agreement provisions when disputes arise regarding a provider's obligations as a participating network provider. The provider agreement should address the most commonly disputed issues and be written in clear, concise language understandable to the provider community.

Provider Manuals

As a preliminary matter, you should obtain a copy of the health plan's provider manual. Provider agreements typically incorporate or reference the provider manual, which often contains detailed discussions of important matters such as credentialing process, claims submission, appeal rights, and maintenance of medical records. As part of the provider agreement drafting process, review the provider manual to make sure that it reflects the most recent legal and regulatory requirements as well as the health plan's unique processes and procedures.

Essential Terms

Health plans compensate providers for covered services provided to members under the terms of the provider agreement. Terms to be included in the provider agreement are set out below. They include information about compensation, billing, payment, network participation, provider licensing and insurance, provider credentialing, maintenance of records, termination, and state contracting and filing requirements.

Compensation, Billing, and Payment

The healthcare claims submission process and subsequent payment to providers are standardized across providers, but the amount of compensation paid to individual providers varies and is typically set out in an appendix to the provider agreement.

Participating providers agree to accept payment from the health plan for clean claims according to terms set out in the provider agreement. Clean claims are defined in the provider agreement, with the definitions most often taken directly from state insurance laws and regulations. It is good practice to set out the health plan's process for handling incomplete claims in the provider agreement or at least to reference where a provider can find that information (for example, the provider manual).

A key point for participating providers is that they accept the agreed-upon payment amounts from the health plan as payment in full for all services provided to plan members. Providers may not balance-bill members for amounts beyond what the health plan pays to the providers for the services provided. In addition, providers agree to collect a co-payment from members, as required under the member's applicable plan design.

The provider contract will set forth time frames within which a provider must file a clean claim with the insurer. Time frames are typically 120 days from date of service but can run up to one year after services are rendered. However, time frames must reflect state requirements. You should review applicable laws to confirm that the

agreement does not hold providers to a time line that is too short and consequently in conflict with state law.

Claims submission is a topic of frequent disputes between health plans and providers. The agreement should specify how the health plan expects claims to be submitted.

If the health plan prefers electronic claims over paper claims, then the agreement might require best efforts by providers to submit claims electronically. The agreement should clearly explain the process for submitting electronic claims, making it as effortless as possible for the providers, and provide any details such as electronic standards. The agreement should also set forth processes for submitting paper claims (often using CMS Form 1500), for when providers are unable to submit electronic claims for technical or other reasons.

For its part, the health plan must pay providers according to state prompt payment laws. The provider agreement must reflect the appropriate prompt payment time lines. If the health plan wants to retain the right to recoup money paid to providers for any reason (e.g., in the event of an overpayment by the health plan to the provider), the provider agreement should clearly set out that right and describe how the recoupment process might work.

The health plan may want the right to deduct any overpayment amounts from future payments due to the provider. If the health plan expects the provider to pay back any amounts owed if no future payments will be due to the provider, the provider agreement should specify how the repayments should be made. State laws limit how health plans can recoup so you should review the applicable state laws when drafting recoupment provisions.

Suspension of payment may also be necessary, if for example a provider is under investigation for suspected fraud or other reasons, and the agreement should explicitly state that.

Network Participation

Also, if the health plan maintains several networks intended for use in different plan designs, the provider agreement should indicate the specific networks in which the provider agrees to participate. Often, the networks are defined in an appendix but for ease of administration, and to avoid the need to amend the provider agreements when new networks are added, the main body of the agreement would indicate that the provider agrees to participate in the networks outlined in the appendix, as well as any other networks that the health plan may add from time to time.

The provider agreement should emphasize the need for the provider to participate in the credentialing process and continuously maintain credentialing. It should also incorporate by reference the health plan provider manual's more detailed discussion of the health plan's credentialing standards.

Provider Licensing and Insurance

Provider agreements must require providers to maintain licenses to practice as a condition of participation in the health plan's provider network. The agreements require continued provider licensing and reporting when their professional licenses are restricted, limited, sanctioned, or revoked.

The health plan should be aware of the timing of any reporting about license restrictions, limitations, suspensions, or revocations so that the health plan can make necessary decisions about provider termination, if necessary, depending on the gravity of the license limitations, sanctions, or revocations.

The health plan should also research its relevant state laws to determine whether it is required to terminate a provider within a certain amount of time after a provider's license is restricted, limited, sanctioned, or revoked. If so, the reporting time lines in the agreement should take such timing into account.

The provider agreement should also set forth the minimum professional liability insurance that the provider should maintain.

Provider agreements should set out as a general principle the necessity of the provider's compliance with any federal, state, local, or other applicable law, as well as the health plan's own policies and procedures. Specific laws may be called out, such as the Health Insurance Portability and Accountability Act (HIPAA), as amended.

In addition to a state license and professional liability insurance, the health plan should also consider the following requirements:

- Active medical staff membership on the medical staff of a hospital or other healthcare facility
- A controlled substance license and Drug Enforcement Administration registration
- Any registrations, certifications, and accreditations required by law to render healthcare services in the state in which services are provided to members

Finally, the provider agreement should clearly list when the provider must notify the health plan—preferably immediately or promptly—of certain key changes in the provider's personal or professional life that by their nature raise concerns about the health or safety of plan members. This allows for the health plan to make a quick decision about the provider's continued participation in the health plan's provider network. Key changes can include the following:

- Indictment, arrest, or conviction
- Suspension or limitation in eligibility to participate in either the Medicare or Medicaid program or any other federal or state healthcare program
- Being a party to a legal action arising out of the practice of the provider's profession
- Restriction, suspension, revocation of medical staff membership and/or clinical privileges, or voluntary relinquishment of medical staff membership or clinical privileges at any hospital or other healthcare delivery setting
- Termination, probation, suspension, or any other adverse action by a regulatory authority in connection with any license, registration, or certification relating to the provision of healthcare services
- Cancellation of professional liability insurance
- Sanctions imposed by a state or federal government for fraud or abuse in connection with a government sponsored health benefit program
- Suspension or revocation of participation in any health benefit plan due to billing fraud or abuse

Provider Credentialing

Health plans are responsible for credentialing and periodically re-credentialing network providers. If a provider is not credentialed or re-credentialed, the provider cannot participate in the health plan's provider network or would be terminated from the network, subject to any rights to cure any deficiencies. Successful credentialing and re-credentialing is a prerequisite to payment by the health plan.

The provider agreement should emphasize the need for the provider to participate in the credentialing process and continuously maintain credentialing. It should also incorporate by reference the health plan provider manual's more detailed discussion of the health plan's credentialing standards.

Maintenance of Records

Medical records are a vital part of a health plan's operations, and the plans rely on their network providers to keep such records. The provider agreement should require providers to keep medical records of their patients in a manner that meets the standard of care for their profession (often reflected in medical professional responsibility rules among other places). Require providers to keep their medical records for at least 10 years, or for as long as required by applicable law. In addition to researching state laws and regulations on medical records retention, consult the health plan's document retention policies and its compliance team for specific guidance on the adequacy of that time frame. Providers must also comply with any applicable medical record privacy and confidentiality laws, including HIPAA and state-specific rules.

Finally, the provider agreement should give the health plan specific rights to access medical records and other books and records relevant to the provider's participation in the provider network. Such provisions typically permit a health plan to access that information at any reasonable time.

You might consider adding language such as "with reasonable notice to provider" and "during provider's regular office hours" because providers sometimes balk at the otherwise broad access rights granted to health plans. This is one place where you can meet them halfway.

Termination

The provider agreement should explicitly list the most common reasons for termination by the health plan with applicable time frames for notice. Notice time frames vary but health plans generally prefer shorter time frames—if they separate from a provider, sooner is often better. However, the time frame should reflect the facts and circumstances.

Particularly important are the triggers for immediate termination. Common reasons for immediate termination are:

- Danger to health and safety of members
- Loss, suspension, or restriction of a provider's license
- Failure to meet the health plan's credentialing criteria
- Failure to maintain professional liability insurance
- Insolvency or bankruptcy of provider

Mutual termination language should also be included in the agreement, with special consideration given to the health plan's need for sufficient time to plan for the departure of a provider from its network. Health plans need to maintain adequate accessibility standards that may require them to replace a departing provider. The health plan will need time to recruit a replacement provider into the network, and that time frame should be incorporated into the termination language.

The provider agreement should also explain any appeal rights that the provider may have upon receiving notice of termination by the health plan (with references to the provider manual, as appropriate).

However, be careful not to create new rights to appeal a termination decision other than those to which the provider is entitled under law or that are set forth in the provider manual or other applicable health plan policies and procedures.

It should be noted that many states make it illegal for health plans to terminate or otherwise retaliate against network providers for actions that are intended to benefit their patients. Provider agreements should reflect these limitations. For example, under Pennsylvania law, provider agreements may not permit the health plan to terminate a provider for, among other things:

- Advocating for medically necessary and appropriate healthcare services for member
- Filing a grievance on behalf of a member
- Protesting a plan decision that the provider believes interferes with the provider's medical judgment[1]

Whether or not state laws explicitly restrict a health plan's termination rights with respect to the above provider behavior or similar behavior, it is generally advisable for a health plan to refrain from doing so because of the negative effects such actions would have on health plan-provider relations, member relations, and public relations. Provider agreements should reflect that approach.

State Contracting and Filing Requirements

Some states[2] require health plans to include specific language as drafted by the health department or insurance department responsible for regulating health plan provider networks. Over time, the administrative agencies periodically amend or add to this language.

Consult the insurance department and health department of the state where the health plan is licensed to determine whether they require model provisions to be included in the provider agreement. Often this language is included as an appendix to the agreement.

Some states require health plan provider agreements to be approved and filed in advance with the appropriate department. For examples, consider Maryland,[3] Pennsylvania,[4] and Washington.[5] Also, if any provisions are changed, the health plan needs to file an amended agreement with the agency.

To avoid administrative agency-related delays associated with refiling amended documents, consider in advance whether the terms of the template agreement apply broadly and whether and how often the provisions may need to be changed.

It should be noted that states that require health plans to file their provider agreements statutorily define those documents as confidential and not subject to public inspection under state freedom of information laws. This additional level of protection can reduce (although not eliminate) a health plan's concerns about losing a competitive edge from disclosure of proprietary elements of its provider agreements. L

Related Content

For additional insight into health plan network provider agreements, see

> **HEALTH PLAN PROVIDER AGREEMENT ESSENTIALS CHECKLIST (COMMERCIAL - HEALTH PLAN)**

RESEARCH PATH: *Insurance > Assessing Claims and Coverage > Types of Insurance > Checklists*

For a discussion on the impact of state health insurance laws on health insurance companies, see

> **EXTRATERRITORIAL STATE REGULATION OF GROUP HEALTH INSURANCE POLICIES**

RESEARCH PATH: *Insurance > Assessing Claims and Coverage > Types of Insurance > Practice Notes*

For a checklist that serves as a starting point for health insurance legal and compliance risk assessment and management planning, see

> **EXTRATERRITORIAL STATE REGULATION OF GROUP HEALTH INSURANCE POLICIES CHECKLIST**

RESEARCH PATH: *Insurance > Assessing Claims and Coverage > Types of Insurance > Checklists*

For information on how antitrust enforcers analyze proposed mergers between health insurance companies, see

> **HEALTHCARE PROVIDERS AND INSURERS: DOJ APPROACH IN INSURER MERGERS AND ACQUISITIONS**

RESEARCH PATH: *Insurance > Advising on Business Transactions > Mergers and Acquisitions > Practice Notes*

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RESEARCH PATH: *Insurance > Assessing Claims and Coverage > Types of Insurance > Practice Notes*

1. 28 Pa. Code § 9.722. 2. Such as in New York, N.Y. Comp. Codes R. & Regs. tit. 10, § 98-1.13. 3. Md. Code Regs. 31.12.02.13. 4. 28 Pa. Code § 9.722. 5. Wash. Rev. Code Ann. § 48.43.730.

Health Plan Provider Agreement Essentials Checklist

This checklist is designed for attorneys representing health plans who are asked to draft or review an agreement with healthcare providers who will be part of the plan's provider network. It highlights key legal and business points for you to consider when preparing a provider agreement for use by a plan.

Assemble Your Project Team. Identify someone at the health plan to connect you with appropriate stakeholders who can answer provider network questions as they arise. While there are preferred drafting techniques for provider agreements, some points will require a judgment call based on the plan's tolerance for risk or its approach to managing provider relationships. You should involve the plan's decision-makers when drafting those provisions.

Schedule a Meeting. It is often helpful to schedule a kick-off call with the provider network team. Whether you are tasked with drafting a new agreement from scratch or with reviewing and revising an existing one, a discussion with the provider network team can help to clarify the plan's approach to provider contracting and where you should focus your attention. You may hear about your client's pain points (i.e., where they have encountered challenges with their network providers in the past) and you can address those issues in the next iteration of the provider agreement.

Obtain Underlying Documents. As you draft or review the provider agreement, you will need to reference some important plan documents:

- ✓ **Provider manual.** Request a copy of the health plan's provider manual (or manuals, if there are different manuals for different healthcare providers). The provider manual explains in detail the policies and procedures that govern the health plan-provider relationship. The relevant provisions of the provider manual will be either quoted directly or incorporated by reference throughout the provider agreement.
- ✓ **Policies and procedures.** Request copies of the health plan's policies and procedures relating to its provider network (for example, provider compensation, billing and payment, credentialing, and records retention policies and procedures). They will provide valuable information when drafting, reviewing, or negotiating the provider agreement.

Draft (or Review) the Provider Agreement. The below topic headings reflect essential provisions of a typical provider agreement. Within each topic are consideration points and discussion prompts for the plan's provider network team. This is not an exhaustive list. Remember to research applicable federal and state laws, administrative agency rules, and guidance materials on these topics to determine if there are specific requirements that need to be addressed in the context of a health plan provider agreement.

✓ **Compensation, billing, and payment**

- Include compensation amounts
- Require provider to accept the agreed-upon payment amounts from the health plan as payment in full for all services provided to plan members
- Define clean claims with reference to applicable state insurance laws and regulations
- Describe healthcare claims submission and provider billing processes
- Set clear time frames within which a provider must file a clean claim with the insurer with reference to applicable state requirements
- Prohibit balance-billing of members by providers for amounts beyond what the health plan pays to the providers for the services provided
- Require providers to collect co-payment from members, where required under the plan design
- Reference applicable prompt payment timelines as provided in state insurance laws and regulations
- Clearly set out any recoupment rights that the health plan will have in the event of overpayments to providers
- Include provisions to allow for suspension of payments as necessary

✓ **Network participation**

- List the specific networks in which the provider agrees to participate
- Include language to facilitate the provider's participation in additional networks, without requiring amendments to the agreement

✓ **Provider licensing and insurance**

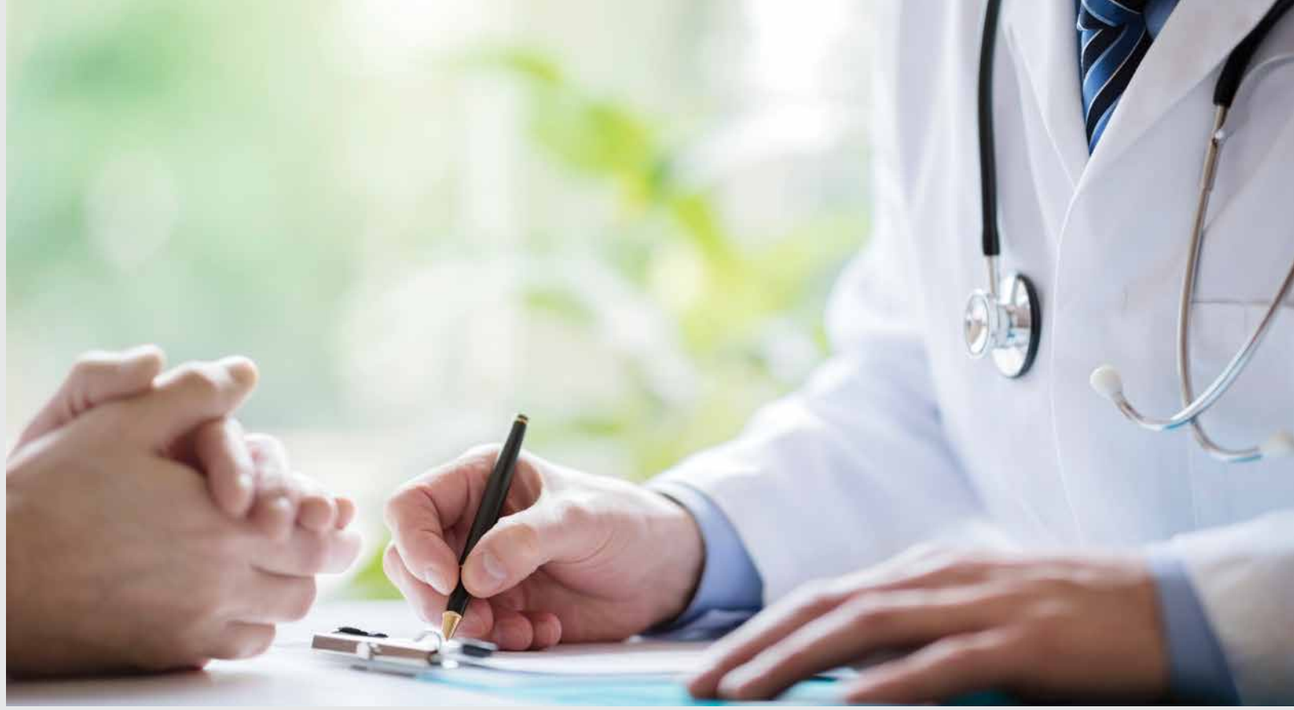
- Require provider to maintain professional licenses
- Specify the minimum professional liability insurance that the provider should maintain
- Require provider to comply with all applicable federal and state laws
- Require active medical staff membership on the medical staff of a hospital or other healthcare facility
- Require a controlled substance license and DEA registration
- Require any registrations, certifications, and accreditations required by law to render healthcare services in the state in which services are provided to members
- Require timely reporting of any license limitations, sanctions, or revocations, or loss of insurance, medical staff privileges, registrations, certifications, or accreditations

✓ **Provider credentialing**

- Require provider to cooperate with the health plan's credentialing process
- If the agreement is with a provider organization as opposed to an individual provider, identify whether the health plan is responsible for provider credentialing, or if credentialing will be delegated to the provider organization
- Require delegated entities to adhere to the health plan's credentialing standards or outside credentialing standards (such as NCQA), where applicable

✓ **Maintenance of records**

- Require provider to create and maintain patient (member) medical records in a manner that meets the standard of care for their profession
- Require providers to keep medical records for at least 10 years, or for as long as required by applicable law



- Require the provider to comply with any applicable medical record privacy and confidentiality laws, including HIPAA and state-specific rules
- Provide health plan with right to access medical records and other books and records relevant to the provider's participation in the plan

✓ **Termination**

- Retain the right for the health plan to terminate provider or to direct a delegated entity to terminate provider
- List the most common reasons for termination by the health plan with applicable time frames for notice to provider
- Enumerate reasons for immediate termination by the health plan
- Include mutual termination language in the agreement, with special consideration given to the health plan's need to plan for provider's departure from its network
- Enumerate provider appeal rights

Distribute Provider Agreement and Schedule Follow-Up Meeting. When the agreement is in good form, distribute it to the stakeholders on your project team. Additionally, a follow-up meeting may help to identify and iron out any remaining issues. On the agenda should be a discussion about any pain points raised in the kick-off meeting and how you have addressed them.

Finalize Document. After making any final changes to the agreement, circle back with the plan's provider network team. There may be logistical issues that require legal input, such as the timing and method of distributing the agreements to providers.

RESEARCH PATH: *Insurance > Assessing Claims and Coverage > Types of Insurance > Checklists*

Brian W. Berglund and Sarah L. Bhagwandin
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Association Health Plans

This article discusses the requirements for Association Health Plans (AHPs) under the Employee Retirement and Income Security Act of 1974 (ERISA) and describes how the final rule issued by the U.S. Department of Labor (DOL) may shape how you advise clients wishing to either establish a new AHP or reevaluate the operations of an existing AHP.

IN PARTICULAR, THIS ARTICLE FOCUSES ON TWO THRESHOLD questions that must be addressed by any association seeking to establish an AHP, in light of the DOL final rule: (1) whether the association qualifies as a bona fide association under ERISA and therefore meets the definition of employer, capable of sponsoring an ERISA health plan; and (2) if the association only qualifies as an employer under the final rule rather than the historical rule, whether it can adopt a viable AHP.[1]

On March 28, 2019, the U.S. District Court for the District of Columbia held in New York v. United States Dep't of Labor, 2019 U.S. Dist. LEXIS 52725 that the DOL's expansion of the definition of "employer" to include associations of employers regardless of their business connection was unlawful. The court set aside that portion of the DOL's June 2018 Final Rule on AHPs. While the defendants may appeal this decision and the full impact is uncertain, be mindful of it when advising clients about AHPs.

Overview of AHP Regulatory Setting

An AHP is a health plan arrangement sponsored by a group or association of employers that have banded together and, collectively, based on DOL criteria, qualify as an employer under ERISA. ERISA governs, with limited exceptions, all employee benefit plans that are maintained by employers, employee organizations, or both.[2] An employer for ERISA purposes is "any person acting directly as an employer, or indirectly in the interest of an employer, in relation to

an employee benefit plan."[3] The term expressly includes a group or association of employers acting for an employer in such capacity.[4]

AHPs are not only governed by ERISA, they are subject to all the laws that regulate health plans, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (ACA). For purposes of the ACA, a qualifying AHP is treated as a single group welfare arrangement, and the number of employees covered by the entire AHP determines the group

1. For a DOL communication on AHPs, *see* Dep't of Labor, About Association Health Plans. 2. ERISA § 4 (29 U.S.C.S. § 1003). 3. ERISA § 3(5) (29 U.S.C.S. § 1002(5)). 4. *Id.*

size. Group medical coverage refers to a single policy issued to a group (like a business with employees). This contrasts with a single policy issued to a single person or family. Under these rules, for ACA purposes, AHPs are treated as offering large group coverage to member employers and therefore are not subject to ACA's small group requirements relating to community rating and mandated essential health benefits.

Finally, AHPs are subject to state insurance laws. A discussion of how state insurance laws impact AHPs is beyond the scope of this article, but practitioners should be aware that state insurance laws will also apply.

Until recently, guidance around what entities may qualify as an association and what it means to act "indirectly in the interest of an employer" had been developed through a somewhat inconsistent hodgepodge of 40 years of case law and DOL advisory opinions. Read together, these authorities narrowly defined which associations could qualify as an employer capable of sponsoring an AHP.

On June 21, 2018, the DOL published its final rule expanding the types of entities that are eligible to serve as an employer qualified to sponsor an AHP.[5] The rule was prepared in response to President Donald J. Trump's executive order "Presidential Executive Order Promoting Healthcare Choice and Competition Across the United States," signed October 12, 2017. That order specifically directed the DOL to consider proposing new rules that would expand AHP availability.[6]

As a result of the final rule, interest in forming AHPs on the part of entities wishing to serve small employers has intensified. At the same time, certain states have become actively hostile toward the expansion of AHPs. For example, 11 states and the District of Columbia sued the DOL in the U.S. District Court for the District of Columbia and partially won on summary judgment. (New York v. United States Dep't of Labor, 2019 U.S. Dist. LEXIS 52725). In some cases, states base their opposition to expanding AHPs on the position that AHPs violate the public policy objectives of the ACA by not requiring the same basic benefit offerings otherwise required by the ACA in the small group market. In other instances, state regulators cite AHPs' checkered history of fraud and asset mismanagement as warranting stricter regulation.[7] Regrettably, this hostility has in some cases carried over to existing AHPs that had been in operation for many years prior to the enactment of the final rule.

As a practitioner, it will be important for you to be able to counsel clients about the DOL's stated objectives for the final rule and the realities around whether your clients' goals can be achieved under either the new or historical AHP rules. Clients seeking advice about forming an AHP or reexamining an existing AHP structure should know that new and existing AHPs can operate under either the new rule or the historical rules.[8]

Basic AHP Structure

An AHP is a health insurance arrangement provided by an association of employers for its employer members. Under the most common structure, the arrangement is fully insured, and the health insurance carrier issues a single group insurance policy to an independent trust established by the association. The individual employer members purchase insurance through the trust and receive a certificate of coverage. Under ERISA, an AHP is considered to be a single employer welfare benefit plan (as that term is defined in ERISA Section 3(1)) that covers multiple employers.[9] As a result, the association files a single Form 5500 for the plan. An AHP is also treated as a multiple employer welfare arrangement (MEWA) and must file a Form M-1 with the DOL.[10]

The Historical Rule and the Final Rule

The final rule substantially relaxes the requirements for qualifying as a bona fide association. However, AHPs that are sponsored by associations that qualify under these relaxed rules must comply with significant new nondiscrimination requirements (as discussed below). When advising clients, you will need to assess whether your client's proposed use of the AHP structure will qualify under the historical rule or the new rule and, if they are seeking to establish an AHP using an association that qualifies under the new relaxed rules, whether, as a practical matter, the client can form a viable and commercially competitive AHP.

What Qualifies as a Bona Fide Association under the Historical AHP Rule?

Under the historical rule, to constitute a bona fide association of employers, the employer members must:

- Have a commonality of interest unrelated to providing benefits
- Exercise control over the benefit plan, both in form and in substance
- Consist of employers with at least one common law employee

Working owners without common law employees (for example, sole proprietors and self-employed individuals) may not be

5. 83 Fed. Reg. 28912 (June 21, 2018). 6. 82 Fed. Reg. 48385 (Oct. 17, 2017). 7. *See* 83 Fed. Reg. 28917. 8. 83 Fed. Reg. 28916. 9. ERISA § 3(1) (29 U.S.C.S. § 1002(1)). 10. *See* ERISA § 101(g) (29 U.S.C.S. § 1021(g)); 29 C.F.R. § 2520.101-2; and Dep't of Labor Form M-1 and instructions. For an agency discussion about MEWAs, *see* Dep't of Labor: Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act—A Guide to Federal and State Regulation.

treated as member employers of an association under the historical rule.[11] A business consisting solely of an individual and his or her spouse is a business without an employee.[12]

In addition, the association itself is required to be a preexisting organization and must exist for a purpose other than providing health coverage to its members.[13]

Commonality of Interest

Determining commonality of interest among employer members is a facts and circumstances test and is based on whether the members of the association have a genuine organizational relationship unrelated to providing health benefits to the employer members. Courts have held that there must be some cohesive relationship between the provider of benefits (the association) and the recipient of benefits under the plan. The DOL has long considered whether the association that maintains the plan and employer members and their employees who benefit under the plan have a sufficiently common economic or representational interest for the association to qualify as an employer under ERISA Section 3(5).[14]

Factors the DOL considers when evaluating whether employer members have a genuine organizational relationship include the following:

- How employer members are solicited
- Who is entitled to participate and who actually participates in the group or association
- The process by which the group or association was formed
- The purposes for which it was formed
- What, if any, were the preexisting relationships of its employer members
- The powers, rights, and privileges of employer members that exist by reason of their status as employers
- Who actually controls and directs the activities and operations of the benefit program[15]

Examples of the kinds of activities the DOL has found to evidence a genuine organizational relationship include when employer members collaborate on resources for educational opportunities, develop joint marketing strategies, and have shared advocacy programs related to the particular industry, to name a few.[16]

11. 29 C.F.R. § 2510.3-3(b). 12. 29 C.F.R. § 2510.3-3(c). 13. ERISA Advisory Opinion 94-07A, 3/14/1994, 83 Fed. Reg. 28918. 14. Wis. Educ. Ass'n Ins. Tr. v. Iowa State Bd. of Pub. Instruction, 804 F.2d 1059, 1063–64 (8th Cir. 1986). 15. 83 Fed. Reg. 28916, footnote 13; ERISA Advisory Opinion 2003-13A,09/30/2003. 16. ERISA Advisory Opinion 2005-24A, 12/30/2005, 83 Fed. Reg. 28918.

The group of employers must direct the operation and activities of the plan through the ability to nominate, elect, and remove a majority of the trustees and/or the ability to amend or terminate the benefit plan. Sole proprietors or other self-employed individuals who are not considered to be employees are not eligible to participate in AHPs under the historical rule.

Further, under the historical rule, benefit programs maintained by employers with no common industry affiliation or that are effectively controlled by a self-perpetuating board with no voice provided to the participating employers do not constitute a bona fide association of employers under the historical rule.[17] Practically speaking, very few association plans were treated as a single ERISA-covered plan under that framework, but instead were treated as a collection of plans each sponsored by individual employers.

What Qualifies as a Bona Fide Association under the Final Rule?

The final rule retains some of the current AHP requirements and modifies or eliminates other existing requirements, as follows:

1. **The rule expands the commonality of interest requirement**. The commonality of interest requirement is significantly expanded to include employers simply related by geography or industry. An association can show a commonality of interest among its members on the basis of geography or industry if the members are either:
   - (i) In the same trade, industry, or profession throughout the United States
   - (ii) In the same principal place of business within the same state or a common metropolitan area, even if the metro area extends across state lines[18]
2. **Sole proprietors can participate in an AHP**. Sole proprietors are permitted to participate in the AHP to provide coverage for themselves as well as their spouses and children, even if they have no employees.[19]
3. **Preexisting organization requirement is eliminated**. The requirement that the association be a preexisting organization is eliminated.
4. **Primary purpose can be providing health coverage**. The requirement that the association exist for a primary purpose other than providing health coverage to its members is eliminated. The final rule does require the sponsoring association to have at least one sustainable purpose in addition to providing health insurance to members, even if the primary purpose of the group or association is to offer such coverage to its members.[20]
5. **Formal organization structure still required**. The final rule retains the requirement that the employer members control the AHP and requires that the AHP have a formal organizational structure with a governing body and bylaws (or similar indication of formality).
6. **Employees of AHP are eligible for AHP-sponsored health coverage**. The final rule now explicitly states that an association is treated as being in the same trade or business as the employer members of the group or association and, as a result, employees of the association itself may participate in an AHP covering the association's employer members.[21]
7. **New nondiscrimination requirements apply**. The final rule adds a new set of nondiscrimination requirements applicable to AHPs.[22] See Nondiscrimination Requirements below.

Note, the portions of the Final Rule that expand the commonality of interest requirement to allow entities to be only related by geography and expands the concept of employer and employee to include sole proprietors have been

17. ERISA Opinion Letter 1994-07A, 3/14/1994. 18. 83 Fed. Reg. 28962. 19. 83 Fed. Reg. 28964. 20. 83 Fed. Reg. 28962. 21. *Id.* 22. *Id.*

> Once formed, building a successful AHP requires patience, persistence, and a continued commitment of significant resources to overcome the practical and commercial difficulties that face startup AHPs.

successfully challenged in federal district court and as of this writing, have been vacated by the U.S. District Court for the District of Columbia in New York v. United States Dep't of Labor, 2019 U.S. Dist. LEXIS 52725.

AHP Nondiscrimination Requirements

When counseling clients who are exploring using the final rule to form a new AHP, you'll need to describe the nondiscrimination rules that apply to AHPs sponsored by associations that qualify under the final rule. The final rule significantly restricts how such an AHP may set rates for employer members. The practical impact of the new nondiscrimination rules is that such AHPs may have difficulty creating a commercially viable health plan.

Employer Experience-Rating Prohibited

The final rule prohibits AHPs seeking to qualify under the new requirements from varying premiums across groups of employers based on health factors. This limitation means that the AHP cannot use experience rating for the employer members except in narrowly defined circumstances. In contrast, under the historical rules, AHPs have been permitted to vary premiums on an employer-by-employer basis, including based on health factors.[23]

Interestingly, loosening the requirements on how to qualify as a bona fide association was intended to ultimately increase the number of small employers that can purchase insurance on terms otherwise only available to large employers. But the final rule's new restriction on experience rating significantly threatens the competitiveness of AHPs—and perhaps their efficacy. Some clients may be seeking to form an association under the new rules without fully understanding how the restrictions on setting rates could undermine the AHP's competitiveness, so this is an important factor to discuss with clients considering the AHP organization.

Commercial Disadvantage

Restricting the use of experience rating when underwriting AHP employer members places an AHP at a significant competitive disadvantage. Commercial insurance carriers are not so limited except to the extent of state and federal community rating requirements that apply to small groups. The practical effect of prohibiting experience rating is that AHPs qualifying under the new rules will be forced to quote basically the same rates for all employer members. This contrasts with commercial carriers being allowed to quote unhealthy large employer groups at higher rates than healthier groups. This is likely to result in adverse selection in the AHP market. Large employer groups with higher-than-average claims will have a financial incentive to join AHPs formed under the new rules, but healthier-than-average groups will inevitably choose to purchase health insurance from commercial carriers. This dynamic could result in AHPs enrolling, on average, more costly groups than carriers in the non-AHP market. If this occurs, the applicable AHP will likely have to increase premiums, diminishing the AHP's ability to attract even moderately healthy groups. This likely scenario may result in further market segmentation and destabilization of the AHP marketplace. Thus, the practical result of this (misguided) nondiscrimination requirement significantly undermines the stated policy objectives of the final rule.

Choosing between the Old and the New AHP Rule to Avoid Nondiscrimination Requirements

Recognizing the problem above, the final rule provides that, where the association qualifies under the historical rule, AHPs may continue to apply experience rating based on health factors to the underlying employer members. Associations formed under the final (new) rule would be required to comply with the final rule's nondiscrimination requirements.[24] New or existing plans that meet the historical AHP qualification requirements need not comply with the final rule's nondiscrimination rule regarding experience rating. Effectively, the requirements in the final rule constitute an alternative method of satisfying the requirements to establishing an AHP. Existing and new

23. 83 Fed. Reg. 28927-28928. 24. 83 Fed. Reg. 28912, 28928, 28962-3.

AHPs need not satisfy the final rule's nondiscrimination requirements as long as they meet the AHP requirements as in effect before the final rule.

If you are advising an existing AHP that wishes to expand within a geographic area, regardless of industry, or to cover a self-employed employer, you'll need to advise the AHP that it will be subject to the new nondiscrimination requirements for setting rates. Any association that wishes to form a new AHP will almost certainly attempt to qualify under the historical rule to avoid complying with the unworkable nondiscrimination provisions. If you are advising an organization that may only qualify as a bona fide association under the final rule and will therefore not have the ability to rate employer members based on health experience, counsel that organization that it will likely face significant challenges in the marketplace as a result of competition and adverse selection by unhealthy employer members.

Forming an AHP

A client seeking to form a startup AHP needs to know that formation requires considerable time, effort, and resources, as well as a strong insurance company partner. Once formed, building a successful AHP requires patience, persistence, and a continued commitment of significant resources to overcome the practical and commercial difficulties that face startup AHPs.

A variety of AHP structures are possible, but the structure described here has worked particularly well in practice.

In whatever structure the client considers, the formation of an AHP will always start with an analysis of the sponsoring association, which will typically serve the role of "plan sponsor" within the meaning of ERISA Section 3(16)(B).[25]

The Trust and Trustees

The common first step is for the association to form a trust. The association will serve as the trust grantor, with individuals who are employed by members of the association serving as trustees. Ideally, three or more recognized servant leaders of their trade, business, or profession will be recruited for the trustee role. These trustees ultimately will be elected by the member firms of the AHP once the AHP is up and running.

The success of the AHP will largely hinge on the dedication, effort, and persistence of the trustees, who, because of ERISA's strictures, must serve without compensation.[26] The individual trustees should therefore be selected from among those who take pride and satisfaction from building something truly special without monetary remuneration for the benefit of employer members and their employees.

Necessary Service Providers

The next step—and perhaps the most challenging for clients—is to contract with skilled and experienced service providers. Their services will be crucial to the smooth day-to-day operation of the AHP. The AHP will need to contract for the following services:

- Billing and collection of premiums
- Marketing and sales
- Preparing legally required participant communications and governmental filings
- Creating and staffing call centers
- Providing internet resources
- Claims processing
- Conducting underwriting
- Establishing robust provider networks and pharmacy benefit management

The Insurance Carrier

The ideal partner is a strong insurance carrier. Forming a successful AHP is probably not feasible without one.

The practical reality is that insurance companies are not that interested in contracting with startup AHPs, so engaging an insurance company partner will be one of the AHP's principle challenges. You can help your client prepare for negotiations with carriers by helping them understand the startup of an AHP from the carriers' perspective. For example, from a carrier's point of view, new AHPs raise the following concerns:

- **High initial cost with little reward.** First, an association that is starting a new AHP will typically require a lot of assistance and expertise from its prospective insurance company partner. This results in the carrier's personnel guiding the process without immediate compensation; the carrier's reward will only materialize if the AHP is successful and the employer members generate profitable revenue to the carrier. In most cases, it takes years for a startup AHP to build up to a sustainable level, without guarantee of success.
- **Employers already using the carrier may simply switch to AHP-sponsored coverage**. If in fact the AHP is successful, it will often cannibalize the existing business of the AHP's insurance carrier partner; employers that already have a group health insurance policy with the carrier may choose to switch coverage to the AHP. Since the carriers typically earn higher profits on their small group business than their AHP business, this is an unwelcome development.
- **State restrictions may disadvantage carriers**. Finally, be aware that in reaction to the DOL's final rule, some states are already seeking to further restrict AHPs under state law. In particular, a few of the blue states have become aggressively hostile towards AHPs and are looking for any excuse to fine a carrier that partners with one or have placed constraints on AHPs to limit their potential growth. For example, California recently enacted SB 1375 to prohibit sole proprietors, partners of a partnership, and their spouses and partners from participating in an AHP.[27] Connecticut issued Bulletin HC-123, stipulating that a small employer, as defined under Connecticut statutes, that participates in a fully insured AHP must be rated as a small employer.[28] Oregon issued Oregon Division of Finance Regulation-Bulletin, No. DFR 2018-06, which provides that any association seeking to establish an AHP in Oregon must satisfy Oregon's requirements for an association.[29]

Clients need to consider why a carrier would ever partner with an AHP. To a large extent, a carrier's willingness to partner with an AHP may be a defensive measure. If the carrier believes that a startup AHP has a good chance of long-term success, then it might be willing to enter into an exclusive arrangement with the AHP to prevent a competitor from doing so. Carriers are likely to evaluate partnering with an AHP startup based, in part, on the following considerations:

- The AHP has demonstrated the will to succeed.
- A substantial small employer membership exists within the association.
- Evidence suggests that the association is committed to the success of the AHP, as demonstrated by the personnel assigned to getting the AHP up and running. Answers to the following questions will be important to persuading the carrier:
  - What are the qualifications of the individual tasked with leading the AHP?
  - Is the AHP leader a strong, entrepreneurial project manager?
  - Has the association provided the project manager with the financial resources to succeed?
  - What is the strength and quality of the association's legal support?
- In the case of a self-insured AHP, the amount of capital the AHP is setting aside as startup capital is critical, as the carrier will be concerned about the AHP's financial ability to continue as an ongoing plan in the event of adverse claims experience.
- Finally, the carrier will typically be much more interested in partnering with a startup AHP that plans to operate in an AHP-friendly state (such as Oklahoma or Texas) versus a state that is actively hostile to AHPs.

25. 29 U.S.C.S. § 1002(16)(B). **26.** ERISA § 408(c)(2) (29 U.S.C.S. § 1108(c)(2)).

27. 2018 Cal Stats. ch. 700. **28.** State of Connecticut Insurance Dept., Bulletin HC 123 (Aug. 27, 2018) (definition of employer under Section 3(5) of ERISA). **29.** Oregon Division of Financial Regulation Bulletin No. DFR 2017–2 (producer compensation for health benefit plans).



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Ambulatory Surgical Center Lease Agreements

WHILE NEGOTIATION OF LEASE AGREEMENTS FOR MOST healthcare providers involves the same issues presented by most commercial lease agreements, this article deals with leases for ambulatory surgical centers (ASCs), which present unique issues that must be identified and negotiated by the attorneys representing the landlord and the ASC tenant. (For purposes of this article, all references to "tenant" shall mean an ASC tenant.) ASCs are healthcare facilities that provide single or multi-specialty outpatient surgical care in the same day, which may include diagnostic and preventative procedures. Given the number of unique economic and non-economic issues that must be addressed, ASC leases can be quite complicated.

Along with discussing key ASC lease provisions, this article offers practical tips for drafting and negotiating an ASC lease from both the landlord's and the tenant's perspectives. This guidance can be used to draft an ASC lease for an entire building or a portion thereof and focuses on the following considerations:

- Predrafting structural considerations (e.g., regulatory environment)
- Rights and obligations with immediate impact (e.g., tenant improvements, utilities, signage, other physical space issues, landlord access to the leased premises, and regulatory compliance issues)
- Those provisions that may not concern the parties until later in the term (e.g., assignment and subletting, permitted and exclusive uses, landlord waivers, and subordination, non-disturbance, and attornment agreements (SNDAs))

Though the main federal and state laws and regulations impacting ASCs are discussed below, the potential impact of state and municipal laws and specific ASC accreditation standards is beyond the scope of this article. Before entering into a lease every prospective investor, landlord, or tenant should consult with a healthcare attorney about potential regulatory risks.

Regulatory Environment and Lease Structure

The healthcare industry is heavily regulated and even minor shifts in laws and regulations can impact lease structure. Landlords and tenants must grapple with restrictive federal and state laws and regulations proscribing kickbacks, rebates, or division of fees between and among physicians and non-physicians, prohibiting the corporate practice of medicine by non-physicians, and prohibiting the offering or receipt of remuneration as an inducement to refer patients. The principal regulatory focal points for landlords and tenants related to ASC leases involve:

- Understanding the regulatory risks for each party
- Allocating such risks appropriately
- Structuring key provisions of the lease in compliance with applicable regulatory requirements
- Ensuring the lease reflects fair market value based on regulatory guidelines

Related Content

For information on which employee benefit plans are subject to the Employee Retirement Income Security Act of 1974 (ERISA), see

> **ERISA FIDUCIARY DUTIES**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > ERISA and Fiduciary Compliance > Practice Notes*

For a discussion on employee benefit plans that are not subject to the requirements of the Patient Protection and Affordable Care Act (ACA) and Health Insurance Portability and Accountability Act (HIPAA), see

> **ACA AND HIPAA EXCEPTED BENEFITS**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Practice Notes*

For an explanation on the rules related to essential health benefits under the ACA, see

> **ACA ESSENTIAL HEALTH BENEFITS**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Practice Notes*

For comprehensive guidance on navigating the wide-ranging, evolving, and frequently complex compliance issues facing employers under the ACA, see

> **AFFORDABLE CARE ACT RESOURCE KIT**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Practice Notes*

Carrier Engaged–Now What?

Assuming that the AHP is successful in engaging an insurance carrier, the carrier will issue a group insurance policy to the AHP. While self-insured AHPs are possible, they are not recommended because of state regulatory hurdles. If the AHP wishes to take on risk, it can do so through a minimum premium contract with a financially sound carrier, in which event the carrier will bear the ultimate risk for all claims costs that exceed premiums and reserves. Advise the AHP as it enters into (1) a services agreement with the carrier and, if the AHP is taking on risk through a minimum premium contract, (2) an experience-rating agreement.

In addition, you will need to prepare a participation agreement that will be used by each participating employer member to contract with the trust under which the employer member will agree to the terms and conditions of trust membership. Once an employer member executes the participation agreement, the carrier will issue a certificate of coverage to the employer member.

Preparing to Advise

Clients who are newly exploring the AHP model for providing health coverage to small employers will need to first decide whether they are best served by establishing an AHP through an existing association that meets the historical rule or whether their employer-group is more likely to use an association that qualifies under the final rule (to the extent it survives the legal challenge.) If your client's proposed association does not qualify as a bona fide association under the historical rule, the client will have to consider the market realities of health insurance to determine if its proposed AHP can compete—and successfully provide—desirable coverage to small employers. L

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RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Practice Notes*

> In recent years, federal and state government agencies have substantially increased their scrutiny of healthcare providers and have also dedicated more resources to investigating and prosecuting violators of fraud and abuse laws...

ASC Lease Referral and Kickback Considerations

When entering into a lease or sublease with a healthcare provider who makes or receives patient referrals from another healthcare provider (particularly for items or services that may be reimbursed by Medicare, Medicaid, or other government healthcare programs), there are a number of federal and state regulations which, if not complied with, present significant risks for civil and criminal liabilities. Due to the nature of these risks, landlords and tenants frequently attempt to obligate the other party to incur some or all regulatory compliance obligations pertaining to the lease. Counsel for both parties should understand the regulatory risks and carefully structure covenants to mitigate such risks. In addition, the lease should contain specific termination provisions triggered by violations of federal or state regulations relating to the provision of healthcare services, loss of requisite licensure, permits, and certifications of the tenant, and breaches of specific covenants (as well as remedies and damages related to violations thereof).

Key Regulations

In recent years, federal and state government agencies have substantially increased their scrutiny of healthcare providers and have also dedicated more resources to investigating and prosecuting violators of fraud and abuse laws, specifically the Federal Anti-Kickback Statute (Federal AKS),[1] the federal self-referral prohibition (Stark),[2] and various state law prohibitions on kickbacks, rebates, division of fees, and self-referrals. Explanations of each of these laws as well as tips for managing related liability risks follow.

Federal AKS

The Federal AKS prohibits the knowing and willful solicitation, receipt, offer, or payment of any direct or indirect, monetary or nonmonetary remuneration (including kickbacks, bribes, or rebates) in return for or to induce or reward the referral, arrangement, recommendation purchase, or lease of items or services that may be reimbursed, whether in whole or in part by Medicare, Medicaid, or other government healthcare programs.[3] The Federal AKS is an intent-based statute but does not require actual knowledge or specific intent to violate.

An ownership interest, discount, or opportunity to invest in the underlying property governed by a lease may constitute remuneration to the landlord and/or the AKS tenant and may implicate the Federal AKS. Federal courts have repeatedly held that the Federal AKS may be violated if even one purpose of an arrangement is intended to induce or reward referrals, purchases, leasing, or orders of such items or services, even if there are other legitimate purposes.[4] Violations of the Federal AKS may result in criminal liability and civil and administrative penalties, including mandatory exclusion from participation in Medicare, Medicaid, and other government healthcare programs.[5] Violation of the Federal AKS is a felony, punishable by imprisonment of up to five years, fines of up to $25,000, or both.[6]

Stark Law

Stark prohibits, with exceptions, a physician who has (or whose "immediate family member" has) a financial relationship with an entity from referring patients to that entity for the provision of designated health services (DHS) if payment for those services may be made by Medicare or Medicaid.[7] A financial relationship for purposes of Stark includes both compensation arrangements with, and ownership or investment interests in, the entity to or from which referrals are made.[8]

A lease may constitute a compensation arrangement under Stark because it involves ownership or investment remuneration between a physician and an entity for which referrals DHS may be made.[9] However, as bundled ASC surgical and ancillary services are specifically exempted from the definition of DHS, a threshold consideration in determining application of Stark to an ASC lease is whether referrals are being made for any DHS not included in the ASC bundle.

State Law Kickback and Referral Restrictions

Leases may also implicate state kickback, rebate, and/or self-referral prohibitions, which may similarly restrict ASC lease activity and which may also apply to commercial and other payor sources. In addition, state law may restrict ownership in health facilities by non-physicians through its corporate practice of medicine restrictions. States may even go so far as to restrict leasing to certain providers or for certain express purposes. The scope and enforcement of state laws can vary significantly, and the state's regulatory environment should be carefully considered before entering into a lease transaction.

1. 42 U.S.C.S. § 1320a-7b(b). **2.** 42 U.S.C.S. § 1395nn. **3.** 42 U.S.C.S. § 1320a-7b(b)(1). **4.** United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000); *see also* United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985). **5.** 42 U.S.C.S. § 1320a-7a. **6.** 42 U.S.C.S. § 1320a-7b(b). **7.** 42 U.S.C.S. § 1395nn(a)(1). **8.** 42 U.S.C.S. § 1395nn(a)(2). **9.** 42 U.S.C.S. § 1395nn(h)(1).

Managing Liability Risks

There are a number of ways for a landlord and tenant to reduce risks associated with implicating fraud and abuse regulations, including:

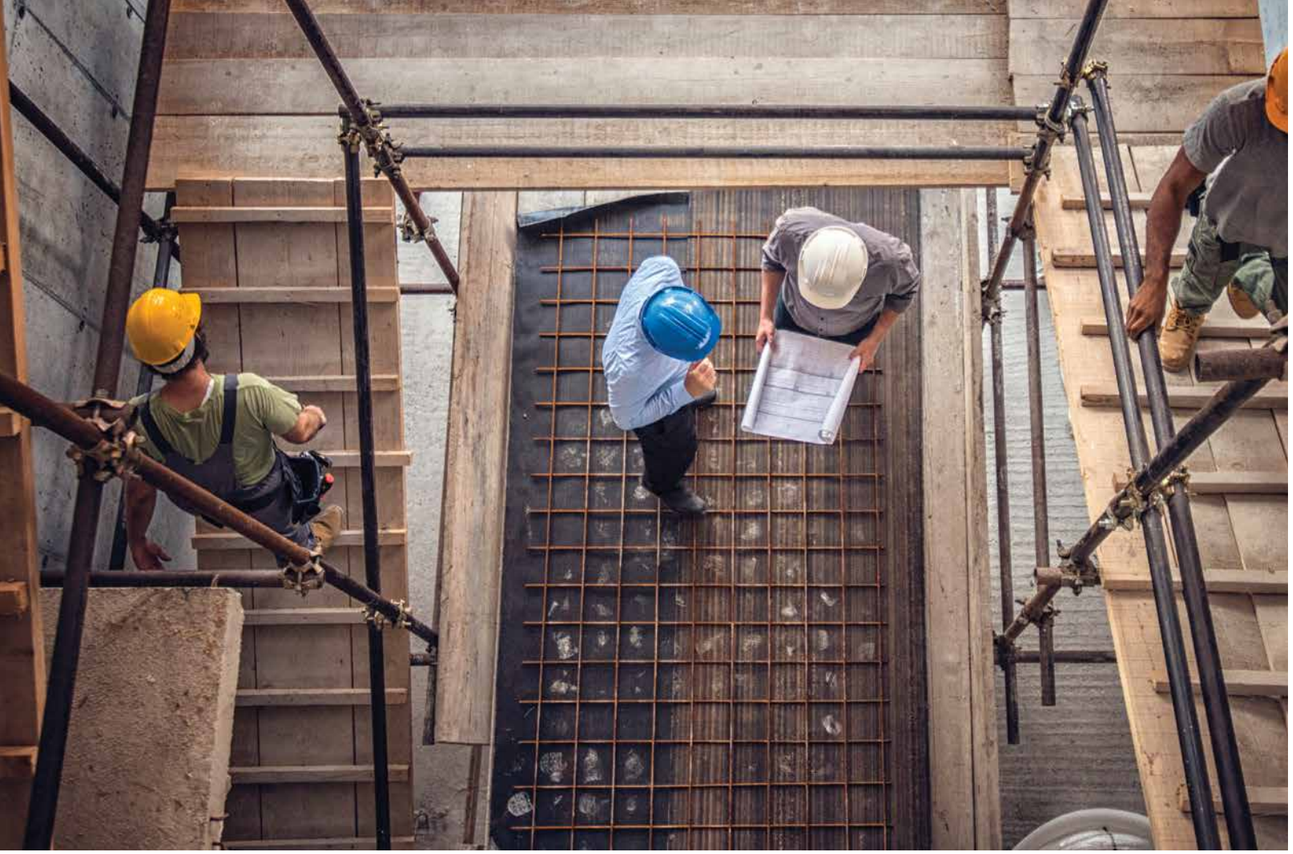
- **Divestiture.** The landlord or tenant may take steps to divest an ownership or investor interest in the property attendant to certain self-referral risks or to prohibit referrals by certain owners or investors in the property to the tenant. However, such steps may not altogether eliminate Stark and state self-referral regulatory risk and will not likely eliminate most risk under Federal AKS and stricter state kickback laws.
- **Use of statutory exceptions and safe harbors.** As discussed further below, the lease can be structured to fit within the Stark space rental exception and the safe harbor provided by Federal AKS (and applicable state) regulations.[10] Recent Stark guidance has added a new exception relative to time-shares;[11] however, this exception does not apply to ASC entities.[12]
- **Setting rent at fair market value.** If the lease does not fit within the Federal AKS (and applicable state) safe harbor and does not violate Stark, the parties should ensure that the base rent is at fair market value and take additional prophylactic measures recommended by the Office of the Inspector General (OIG), albeit with significantly higher risk under the Federal AKS.

Space Rental Exception and Safe Harbor

The general requirements under the Federal AKS safe harbor and the Stark exception share many of the same features. To satisfy both, the arrangement must:

- Be set forth in writing
- Be signed by both parties
- Describe the specific space to be leased
- Establish a term of at least one year
- Be for an aggregate rent amount set over the term of the lease
- Be consistent with fair market value
- Satisfy a commercially reasonable business purpose
- Not be determined in a manner that takes into account the volume or value of referrals
- Be commercially reasonable in the absence of any referrals
- Be for the lease of only such space as is reasonably necessary to accomplish the commercially reasonable business purpose of the rental
- Any holdover month-to-month rental following the initial one-plus year term must meet the same conditions as above[13]

10. *See, e.g.*, 42 C.F.R. § 1001.952 and 42 C.F.R. § 411.355. **11.** 42 C.F.R. § 411.357(y). **12.** 80 Fed. Reg. 70886, 71325–71327 (Nov. 16, 2015). **13.** *See* 42 C.F.R. § 1001.952; 42 C.F.R. § 411.355.



Fair Market Value in Lease Arrangements

The critical issue for tenants and landlords is whether the base rent and any build-out costs are consistent with fair market value (FMV). The Centers for Medicare & Medicaid Services (CMS) defines FMV in a lease as "the value of a rental property for its general commercial purposes."[14] CMS has provided guidance indicating several key restrictions on this general value, including:

- The amount may not take into account the property's intended use.[15]
- The amount may not be upwardly adjusted to reflect the value that either the prospective tenant or landlord places on the property as a result of its proximity to sources of referrals or other business.[16] In other words, a landlord may not seek or charge a commercially unreasonable rent for an ASC located near a medical office park or hospital because such proximity may generate additional referrals.
- While the landlord may take into account additional costs for leasehold improvements for development or upgrading of the leased premises, the landlord may not provide capital improvements and build-outs that are more valuable than those that would be provided to any other tenant unless such costs are properly allocated to the tenant.[17] Under an ASC lease, any build-out costs for imaging services or operating rooms should be borne by the tenant. CMS has opined that the determination of whether any costs of capital improvements should be allocated over the useful life of the improvements or be passed on in their entirety to the tenant will depend on the facts and circumstances of the case.[18]
- The base rent should be fixed in advance and should not vary with volume or value of referrals or be based on a percentage of revenue raised, earned, billed, collected, or otherwise attributable to the services performed on any business generated through the use of the space. The OIG does not view per-unit compensation relationships to be set in advance under the Anti-Kickback Statute. In essence, the annual aggregate rent must be determined and reflected in the lease to be considered set in advance for purposes of meeting the space rental safe harbor.

14. 42 C.F.R. § 411.351. 15. *Id.*; *see also* 66 Fed. Reg. 856, 945 (Jan. 4, 2001). 16. *Id.* 17. *Id.* 18. 72 Fed. Reg. 51012, 51045 (Sept. 5, 2007).

In determining FMV, CMS provides that documentation of comparable public transactions may be a commercially reasonable method for establishing reasonable base rent per square foot (subject to additional adjustments for capital improvements by landlord).[19] However, due to the substantial investment often involved in building out an ASC space, which may subject an ASC lease to additional scrutiny, the best practice is to obtain an independent third-party appraisal. Although an appraisal is not expressly required by Stark or Federal AKS, the parties should consider engaging a qualified and independent third-party valuation firm with experience appraising ASC space rentals to ensure FMV is paid. CMS has indicated that it believes internally generated appraisals to be particularly susceptible to manipulation and may subject such internal surveys to additional scrutiny that might not otherwise apply to an independent third-party valuator.[20]

ASC Licensure and Certificate of Need (CON)

Attorneys for both parties should ensure that their clients also thoroughly understand applicable state regulatory requirements prior to entering into the lease, with particular attention paid to any contingencies in the lease related to CON requirements. Many states require that an ASC obtain a CON through a market-restrictive process demonstrating that the proposed ASC fulfills public need for and requirements of state health planning boards. If a state requires CON approval for establishment of an ASC, a tenant and landlord may seek to make the effective date of the lease contingent on approval of a CON (or other requisite licensure), with delivery of possession of the leased premises to the tenant subject to this condition. Any such contingencies must be carefully drafted to provide limits on how long a landlord may be subject to hold the premises prior to delivery. Certain states may also impose notice and other requirements in the event of a proposed closure of an ASC and the attorney for the tenant should ensure that the lease is drafted to reflect and comply with any such requirements.

Most states also license ASCs and promulgate extensive practice restrictions and physical facility requirements in addition to those provided in Medicare or accreditation standards. The Accreditation Association for Ambulatory Health Care and The Joint Commission, whether acting as deemed status surveyors or accrediting an ASC, often have further physical layout requirements that may exceed state requirements. Some states do not place ASCs in the licensure category and instead regulate them as hospitals or office-based surgery practices or clinics. A state may also restrict entry to an ASC market by and through a legislative or administrative moratorium. For example, New Jersey continues to have a regulatory moratorium on the establishment of new ASCs in the state, subject to certain exceptions.[21]

ASC Space Sharing Arrangements

Subleases by tenants and block leases permitting the sublease of a portion of a facility are common among healthcare providers where space sharing is permitted, but, in an ASC context, landlord's counsel must be careful to ensure that space sharing is, in fact, permitted and, if so, the times and scope meet all ASC space sharing requirements. As discussed below, tenants are reluctant to limit their assignment and subleasing rights because they may wish to enter into a space sharing arrangement that reduces fixed-cost build-out and investments, reduces personnel, administrative, and equipment overhead, and endeavors an additional medical tenant to cover a portion of the rent

Federal Space Sharing Requirements

The federal Conditions for Coverage do not generally require that an ASC be housed in a separate building from other healthcare facilities or practices. However, an ASC is defined by federal law as a separate and distinct entity that operates exclusively to provide surgical services (State Operations Manual (SOM), Appx. L, § 416.2), and which must be separate and distinguishable from any other healthcare facility or practice (SOM, Appx. L, Pt. II, Q-0002) either (1) physically or (2) temporally. Thus, under federal law (subject to some restrictions), a physically or temporally separated ASC may share space with another entity.

The Medicare SOM notes that (1) a physically separate, "distinct entity" must be separated from other facilities by a wall meeting certain fire proofing requirements, and (2) a temporal distinction permits an ASC to share the same physical space insofar as the ASC and other entity "are separated in their usage by time" (SOM, Appx. L, § 416.2). In other words, an ASC operating four days a week as a single specialty nephrology ASC and one day per week as a vascular access center or extension of the same or as other interventional nephrologists' practice(s) would satisfy these requirements. But the same ASC could not lease, during its hours of operation, clinical space to the physician or practice to operate concurrently, as such entities would not be "separated in their usage of time."

Additional Space Sharing Considerations

When assessing the propriety of an ASC space sharing sublease arrangement, there are a number of additional considerations. State law may substantially restrict or proscribe outright an

19. 66 Fed. Reg. 856, 944–945. 20. *See, e.g.*, *Id.* 21. *See* N.J. Stat. Ann. § 26:2H-12.

Related Content

For suggestions for negotiating the lease of space for medical use and resolving concerns that commonly arise in such leases, see

> **COMMERCIAL LEASES FOR MEDICAL USE**

RESEARCH PATH: *Real Estate > Commercial Leasing > Lease Agreement > Practice Notes*

For an explanation on the principal forms of expansion rights provisions in commercial leases, see

> **EXPANSION RIGHTS PROVISIONS IN COMMERCIAL LEASES**

RESEARCH PATH: *Real Estate > Commercial Leasing > Lease Agreement > Practice Notes*

For guidance in drafting a commercial or industrial lease agreement, see

> **COMMERCIAL AND INDUSTRIAL LEASE**

RESEARCH PATH: *Real Estate > Commercial Leasing > Lease Agreement > Forms*

For a sample lease of space for use as a medical facility, see

> **MEDICAL OFFICE SPACE LEASE (TENANT OBLIGATED TO DISPOSE OF INFECTIOUS MEDICAL WASTE)**

RESEARCH PATH: *Real Estate > Commercial Leasing > Lease Agreement > Forms*

For assistance in drafting a lease for a medical facility that permits or prohibits specific medical uses, see

> **USE AND OCCUPANCY CLAUSE (LIMITED MEDICAL USE)**

RESEARCH PATH: *Real Estate > Commercial Leasing > Lease Agreement > Clauses*

ASC space sharing arrangement under its licensure or other applicable regulations. Where not outright proscribed, states often do so by limiting operation of more than one license in a particular location. For example, in New Jersey, an ambulatory surgery facility is defined as "licensed as an ambulatory surgery facility, separate and apart from any other facility license. . . . The ambulatory surgery facility may be physically connected to another licensed facility, such as a hospital, but is corporately and administratively distinct."[22] This provision has been interpreted by state regulators to proscribe ASC space sharing in the state.

Even where states permit space sharing arrangements, tenants and landlords should notify state and accreditation surveyors of the hours of operation for each supplier. If a holder of interest in the space sharing entity or practice also has an investment interest in the tenant or the landlord and is in a position to make referrals to the ASC, this will likely implicate fraud and abuse regulations and potentially render the lease in violation of applicable federal and/or state law. Direct and indirect ownership, investment, and/or referral arrangements may subject a tenant to higher scrutiny under any sublease arrangement unless the arrangement is carefully structured in accordance with an exception or Federal AKS (and applicable state) safe harbor.

Subject to state law, federal regulations also permit temporally distinct entities to share waiting rooms, reception areas, restrooms, staff break rooms, and other common areas. A space sharing tenant may allocate some shared common area costs (including build-out costs therewith) to the other entity insomuch as the allocation does not exceed the person or entity's proportional use of the ASC premises. However, not all space may be shared. The lease or sublease should include additional prophylactic measures to ensure compliance with all applicable laws and regulations. For example, the lease should require that signage be changed out on the days the tenant is not operating as an ASC so as to meet applicable state licensure and marketing requirements. The lease should also provide that medical/administrative records and electronic health records must remain physically separate from and inaccessible to the sharing entity so as not to run afoul of the Health Insurance Portability and Accountability Act (HIPAA) or the Health Information Technology for Economic and Clinical Health (HITECH) Act or applicable state medical records requirements regulating the disclosure and security of medical records.

Prior to or during lease negotiations, the landlord and the tenant must also narrowly define both common and restricted space because a facility's physical space layout can significantly alter the attendant regulatory analysis.

Negotiating Key Provisions in ASC Leases

Permitted and Exclusive Uses

The permitted use provisions of an ASC lease are often the subject of heavy negotiations by the parties. Landlords generally try to limit the permitted uses to be very specific, particularly where the ASC will be leasing space in a multi-

22. N.J. Admin. Code § 8:43A-1.3 (emphasis added).

tenanted building. The permitted use provision must accurately capture the tenant's intended use of the leased premises, without being overly narrow, so as to prohibit the tenant from using the space for purposes incidental to the operation of an ASC on the leased premises. Moreover, the tenant needs to consider the likelihood of later assigning or subletting all or some of the leased premises, as a permitted use provision that is drafted too narrowly may ultimately prevent the tenant's ability to assign or sublet space to a third party.

Whether or not the tenant has an exclusive use right is a business point that is also typically heavily negotiated by the parties. Landlords are typically reluctant to give an exclusive use right, while tenants will want assurances that no other ambulatory surgery or treatment centers will be operated on the property. Accordingly, if the landlord agrees to give a tenant an exclusive use right, the language must be narrowly and precisely drafted to provide the tenant with adequate protection without unduly restricting the landlord's ability to operate and lease space to other tenants in the same and adjacent property and must also avoid infringing on any the exclusive use rights of any existing tenants.

If the landlord and/or its affiliates own or control other properties in close proximity to the leased premises, the tenant may also desire a radius restriction, which prohibits the landlord and its affiliates from permitting any other tenant or occupant of such properties to operate an ambulatory surgery or treatment center. The tenant's motivation is both to (1) minimize regulatory risks, as discussed above; and (2) avoid losing patients and business for the ASC due to other, competing providers operating nearby the ASC premises. Before agreeing to such a restriction, the landlord must consider not just the current tenants of its and its affiliates at nearby properties, but also the ability to lease available space to suitable tenants in the future.

Hours of Operation

Unlike medical practices and general commercial tenants, an ASC's hours of operation need to be more flexible to allow for (1) performance of surgical and pre-operative procedures before ordinary business hours and (2) extended recovery time and other post-surgical care that may need to be furnished after ordinary business hours (potentially including weekends). Therefore, when representing a tenant, it is critical that the attorney understands the required hours of operation for the ASC to conduct its business. Moreover, the attorney representing the landlord must verify whether it is feasible for the landlord to provide required services during extended hours of operation and that the other tenant's rights of use will not be unreasonably interfered with or disturbed prior to agreeing to accommodate the tenant's requested operational schedule.

Tenant's Right to Make Alterations, Additions, and Improvements

The alterations provision of the lease sets forth the tenant's ability to make changes to the leased premises during the lease

term. In general commercial leases, the typical alterations provision requires the landlord's consent to make alterations other than purely decorative and cosmetic changes that are nonstructural or cost less than a certain amount (e.g., $5,000) in any one instance. However, in the context of ASC leases, the alterations provision is often the subject of heavy negotiations between the parties, as the installation of surgical equipment and the other specific improvements and alterations, many of which involve structural alterations, will be necessary for the operation of an ASC, particularly if the leased space has been designed or previously used for another purpose. Accordingly, it is generally best for the parties to agree on a specific plan for the initial build-out, improvements, and installation of equipment in the leased premises before executing the lease.

Because tenants will likely need to (1) replace existing surgical equipment, (2) install new surgical equipment during the lease term, and (3) make other alterations to the space during the lease term to account for business needs or comply with legal or accreditation requirements, the parties need to negotiate an alterations provision that takes this into account and provides sufficient protection for both parties. The tenant will want reasonable assurances that the landlord will timely accommodate these needs without unreasonably withholding necessary approvals, while the landlord will want the right to review and approve the tenant's proposed alterations, particularly those with structural implications or that will require costly alterations to re-let the property to non-ASC tenants at the end of the lease term.

A crucial aspect of the alterations provision is what alterations and improvements, if any, the tenant will be required to remove at the termination or expiration of the lease. This concern is particularly acute in the ASC lease context, as the improvements and alterations required to operate an ASC are often not conducive to general commercial use of the space, can be very costly to undo, and result from the ASCs' installation of expensive surgical equipment in the leased premises that may be subject to third-party financing. Therefore, it is critical that the parties agree up front as to:

- What alterations and improvements the tenant will be required to remove, if any
- Whether the tenant is required to restore the space to a condition more suitable for general uses at the end of the lease term
- If the tenant is required to restore the space, who will bear the associated costs and expenses

Tenant's Signage Rights

The lease should set forth the tenant's signage rights. To comply with applicable laws and regulatory and accreditation requirements, as well as for general business purposes, tenants will typically want the right to (1) install and maintain signage on the exterior of the building and the property, any monument or pylon sign for the building, and on the doors and interior of the building; and (2) have the ASC and its associated physicians listed in any directory for the building or property. Depending on what the parties negotiate, the tenant will typically pay for some, if not all, of the expenses of the signage and its installation. Such signage (including its design and placement) is almost always subject to the landlord's prior approval. However, the tenant will typically want the landlord to agree in the lease to the ASC's proposed signage package, which is often attached as an exhibit to the lease. The tenant will usually also want the ability to change or install additional signage during the lease term (with the landlord's consent), and thus may want to restrict the amount of time the landlord has to review and approve proposed signage, which approval should not be unreasonably withheld, conditioned, or delayed.

Additionally, due to the importance of having visible signage for an ASC, the tenant should consider negotiating (1) a prohibition or restriction in the lease on the landlord's ability to install structures that block the visibility of the tenant's signage and (2) a provision that requires the landlord to install temporary signage and take other mitigating actions to limit disruption for the limited and temporary periods (such as construction and repairs) where it is unavoidable. Furthermore, the lease should clearly delineate which party is responsible for removing signage installed by the tenant at the end of the lease term and for paying the associated costs and expenses.

Landlord's Access to the Premises and Landlord's Repairs and Improvements

By nature of the sensitive medical procedures performed at an ASC, the lease should clearly spell out who, when, and under what circumstances the landlord has the right to access the ASC premises, whether to conduct repairs, maintenance, inspections, or improvements. Unexpected interruptions or interference by the landlord or its agents could have serious, and even potentially deadly, consequences. Accordingly, the tenant will want to make sure that the landlord's right to enter onto the premises and to conduct repairs, maintenance, or improvements within the premises is conditioned on at least 24 hours prior notice (except in cases of emergency), in a manner that will minimize any disruption or interference with the tenant's use and operation of the premises for surgical procedures. To do so, the parties should build some flexibility into the lease to allow the landlord access to the premises both during and outside of the ASC's normal business hours, depending on the reason the landlord needs access and the potential disruption or interference with the ASC's operation. Similarly, a tenant will also want to negotiate reasonable rights

Additionally, the tenant's attorney must be cognizant of the requirements imposed under HIPAA, HITECH, and related state medical records privacy and security laws when negotiating what rights the landlord will have to enter onto the ASC premises.

to restrict (or at least, to have to consent to) the landlord's performance of certain types of improvements, inspections, maintenance, and repairs in other areas of the building or property near the ASC premises, as byproducts such as noise and dust can adversely affect the performance of surgical procedures and furnishing of patient care at the ASC.

Additionally, the tenant's attorney must be cognizant of the requirements imposed under HIPAA, HITECH, and related state medical records privacy and security laws when negotiating what rights the landlord will have to enter onto the ASC premises. The tenant will need sufficient prior notice from the landlord in order to provide the ASC with adequate time to take precautionary measures to protect, safeguard, and restrict access to patient records and other confidential materials on the premises from unauthorized access or removal from the premises. Moreover, the tenant may want reasonable assurances from the landlord that any personnel and agents with access to the premises understand and have received instruction on the privacy and security requirements to which the ASC is subject. The tenant should also seek the right to indemnification from the landlord in the event that the ASC incurs any liability for noncompliance with those legal requirements due to the acts or omission of the landlord, or its personnel or agents, as a result of their access to or presence on the premises.

Assignment and Subletting

Assignment and subletting provisions are some of the most heavily negotiated provisions in any commercial lease and are often even more critical for an ASC lease. Due to the inherent nature of the ASC business, the physicians who own or are affiliated with the ASC may change frequently during the lease term and fundamental transactions (such as mergers, consolidations, and sales of the ASC or substantially all of its assets) are commonplace. Moreover, ASCs often like to sublet or share space with both affiliated and third-party physicians and practices. For example, an ASC may want to sublet one of its operating rooms to another practice on a full- or part-time basis, or may wish to sublet a dedicated portion of the leased premises to an affiliated physician, practice, or management company for their exclusive use as office space. Therefore, the tenant will want to make sure the lease provides sufficient flexibility, while the landlord will want to ensure that any occupants of the space are high quality and have sufficient financial means to pay rent and perform all other obligations required under the lease.

Typically, the tenant should be permitted to, without the landlord's consent, assign the lease or sublet the premises to an affiliate, subsidiary, or successor in connection with a merger, acquisition, or consolidation of the ASC or a sale of all or substantially all of the ASC's assets, so long as:

- The tenant is not in default under the lease.
- The tenant remains liable under the lease.
- The successor tenant's or subtenant's financial position is at least substantially comparable to that of the tenant prior to such event.

The parties should also consider negotiating a threshold percentage change in the ownership or voting interests in the tenant, such that the landlord's consent is not required for any changes thereto over a continuous period (e.g., 12 months) that does not exceed the agreed-upon threshold. Additionally, the tenant may want the lease to specify certain parties (or types of entities and individuals) to which the ASC may assign the lease or sublet space, particularly when the tenant reasonably anticipates a likely need to do so during the lease term.

Generally, the tenant's attorney should seek to ensure that any right of the landlord to consent to an assignment or sublease should not be unreasonably withheld, conditioned, or delayed, while the landlord's attorney should try to include terms in the lease that specify the information that the tenant will need to provide in connection with a proposed assignment or sublease and the applicable time frame. The tenant may want to negotiate inclusion in the lease of a specific, limited list of reasons for which the landlord may permissibly withhold consent (put another way, where the landlord's withholding of consent would be reasonable), although the landlord will often try to insist that any such list not be exclusive. The tenant's attorney should also consider negotiating a provision to the effect that if the landlord fails to respond to a subleasing or assignment request within a specified time frame, the

landlord's consent will be deemed given. The landlord's attorney should also consider negotiating a lease provision that requires the tenant to pay the landlord's reasonable costs and expenses (or, alternatively, a specific, negotiated fee) in connection with the landlord's evaluation of a proposed assignee or subtenant.

Landlord Waivers, SNDAs, and Estoppel Certificates

Due to the high costs of procuring and installing the necessary surgical equipment and operating an ASC, ASCs are typically highly reliant on third-party financing arrangements, especially when the ASC will be required to bear the considerable expenses of converting general commercial use space for the specific needs of operating an ASC. Whenever possible, a tenant should ideally negotiate the terms of any necessary financing prior to (or at least, contemporaneous with) negotiation of the lease and, to the extent possible, arrange for the lender to be actively involved with and participate in the lease negotiation. Although specific requirements may vary by lender, lenders often require execution of the following:

- A landlord waiver, whereby the landlord agrees to waive (or agrees to subordinate in favor of lender) any lien on or security interest in the tenant-borrower's leasehold improvements, equipment, and other assets located on the leased premises, and which grants the lender the right, on reasonable prior notice to landlord, the right to enter onto the lease premises and repossess the tenant/borrower's assets
- A collateral assignment of the lease, whereby the tenant/borrower pledges its rights in, to, and under the lease as collateral security to the lender for repayment and the lender has the right to assume the tenant/borrower's rights in, to, and under the lease as of (but, generally, not prior to) the date of the tenant/borrower's default in its obligations to the lender
- A short form memorandum of lease between the landlord and the tenant, which is recorded in the local land records of the leased premises' jurisdiction and puts subsequent parties on notice of the existence of the lease and the landlord's and tenant's respective rights and interests thereunder

Because landlords often dislike these types of agreements and because their negotiation can be both time consuming and expensive, it is best to negotiate these agreements and any other requirements of the lender simultaneous with, or prior to, the execution of the lease. If the lease must be executed before the ASC obtains necessary financing, the tenant's attorney should consider, at a minimum, negotiating adequate provisions in the lease that require the landlord to execute documents reasonably required for the tenant to obtain required financing. Better yet, the tenant's attorney should include mutually agreed-upon form documents as exhibits to the lease, which the landlord is required to execute on request. What the tenant's attorney wants to avoid, if at all possible, is a situation where a lease is executed without adequately providing for lender requirements, as the landlord will likely insist on costly concessions from the tenant in exchange for what amounts to a giveaway of the landlord's rights with little to no value to the landlord.

Meanwhile, the landlord's attorney also needs to be mindful of preserving the landlord's rights regarding current and future financing arrangements and future sales of the property when negotiating an ASC lease. The landlord's lender will (and a prudent tenant also would) require execution of an SNDA by and among the lender, the landlord, and the tenant, whereby, generally:

- The lender agrees that, even if the landlord defaults on its mortgage and the lender forecloses, the lender will respect the tenant's lease on its terms (Non-Disturbance)
- The tenant agrees and acknowledges that, subject to Non-Disturbance, the tenant's lease rights are subordinate to the landlord's mortgage in favor of the lender (Subordination)
- The tenant agrees to, subject to Non-Disturbance, pay rent, and otherwise honor the terms of the lease notwithstanding foreclosure by the lender (Attornment)

To avoid potentially lengthy and costly negotiations, it is in the best interest of both the landlord and the tenant to include (1) sufficient language in the lease that requires the parties to execute an SNDA on the landlord's or its lender's request with agreed-upon terms, and (2) a mutually agreed-upon form SNDA as an exhibit to the lease. Better yet, if the landlord has existing financing in place to which the ASC premises is subject, the landlord's attorney should seek to attach the lender's approved form of SNDA as an exhibit to the lease.

Similarly, any potential buyer of the property (and, likely, the potential buyer's lender), will insist that the landlord-seller obtain from its tenants (or, at least, its major tenants, of which the tenant will likely be one) estoppel certificates. Although the required provisions of estoppel certificates may vary, they often include a statement and acknowledgment from the tenant of all of the following:

- The lease term, base rent, leased premises, the date through which rent has been paid, and the security deposit
- That the lease is in full force and effect, and has not been modified or amended except as otherwise specifically stated in the estoppel certificate
- That there are no current defaults, conditions, events, or circumstances that would lead to a default, by either landlord or tenant
- That the landlord and tenant have performed all of their respective obligations under the lease to date
- That the tenant has not paid rent or any other charges more than one month in advance
- That the tenant has no right to deduct or offset any amount from the rent or otherwise due to landlord
- That the tenant has no defenses to enforcement of the lease
- That the tenant has neither received from the landlord nor given to the landlord any notices of default
- That the tenant has neither made nor currently has any claims against the landlord

To minimize the cost and time of negotiations, it is in the best interest of both the landlord and the tenant to include sufficient language in the lease that requires the parties to execute an estoppel certificate with certain matters to which the tenant must certify on the landlord's request. Alternatively, the landlord's attorney should seek to attach an approved form of estoppel agreement as an exhibit to the lease.

Physical Facility Issues

There are myriad certification, state, and accreditation standards related to the ASC's physical facility and environment that must be discussed by the negotiating parties to ensure that the tenant's right to make alterations, additions, or improvements is drafted with sufficient breadth to permit the tenant to meet the regulatory requirements to which it is subject. The landlord will want to require transparency regarding the nature and purpose of the intended use of the property, as the tenant will be exposing the property to environmental liability for medical and biological waste, hazardous chemicals, pressurized gases, and controlled pharmaceutical substances, among other items.

As part of the physical facility issues, the landlord's and tenant's counsel will want to consider and discuss handling some of the following issues:

Additional Usage

Tenant's counsel should ensure that the tenant can undertake additional usage of certain utilities and other amenities without disproportionate cost to tenant. The tenant should seek to refine the applicable usage formula to normalize excess allocations. The following is a list of some items that may require additional usage allocations:

- **Utilities.** Counsel should anticipate the need of tenants for uninterrupted utility services, excess electrical, water, HVAC, emergency generators for power failure, and other uses of the ASC. ASCs typically require a much more significant use than standard office tenants of electrical, HVAC, and water facilities, due to the higher utilization needs of the ASC's equipment and hygienic systems. Furthermore, unlike some types of commercial tenants that could temporarily relocate to another office or have their people work from home on a limited basis, the tenant cannot operate, literally, if the utilities and other important building services are not fully and adequately available at all times. Accordingly, the tenant will want to negotiate a provision in the lease that allows the tenant to (1) abate rent if the utilities or other important building services are interrupted or otherwise unavailable for a specified period of time, (2) exercise self-help if the landlord cannot or will not address/repair the problem in a timely manner, and (3) terminate the lease if the problem is repetitive or anticipated to continue.
- **Security.** When security for the property is provided by the landlord, additional security related to the tenant's use of the property may be required for the tenant, particularly in the context where an ASC houses expensive medical and surgical equipment, controlled pharmaceutical substances, patient records, and hazardous chemicals. Additional security costs may include the cost of personnel, fixtures for cameras, and monitoring services.

Additional Build-Out Costs

To ensure that the tenant can meet the requirements of additional build-out costs and financing requirements, the tenant should seek to refine the standard capital improvements provisions in a general commercial lease. The following is a list of some items that may require additional build-out costs:

- **Fire standards.** Reinforced floors, walls, and doors that meet local, state, and accreditation standards may require additional build-out, fixtures, and structural improvements for ASC tenants. For example, if an ASC is co-located with another provider, the National Fire Protection Association Life Safety Code requires that ASCs must be separated from other facilities with one-hour fire walls.
- **Emergency generator.** ASC tenants require uninterrupted power to certain core systems, such as life support, certain equipment, fire, and utility systems. These requirements necessitate the additional expense of building out emergency backup systems, such as an emergency generator. Elevators may also require additional emergency operation and power failure needs.
- **Americans with Disabilities Act (ADA) requirements.** Tenants may require special accessibility needs in and around the premises to comply with ADA requirements to which they are subject.[23] Assuming compliance with the requirements is not "structurally impracticable",[24] most landlords should be familiar with basic accessibility features sought by tenants, such as excess door width, handicapped parking, ramps, lift equipment, water fountains, security systems, and many others.
- **Parking.** Most ASCs are subject to requirements related to reserved spaces for handicapped access and minimum parking availability requirements related to the size of the facility. In some states, local fire, zoning, curbing, public access, or even canopy requirements can necessitate additional space needed to comply with the tenant's needs.
- **Entrances and exits.** Entrances and exits in an ASC must typically comply with various accreditation, licensure, and local requirements related to fire and ADA safety standards. In addition, access restrictions and security cameras must often be provided at entrances and exits to an ASC, which may require additional fixture build-out.
- **Equipment.** Specialized equipment such as imaging equipment used for surgical procedures may require a special build-out and fixturing allocation. Whether the tenant has purchased the equipment at its own cost or through additional financing, the tenant may need a waiver of any rights, lien, or security interest that the landlord may possess with regards to the equipment if the tenant hopes to retain the equipment or return it to the financer following termination of the lease. The landlord may seek to retain some interest in the equipment or other financial assurances in the event that the tenant abandons the property and may attempt to allocate to the tenant the cost of the landlord's removal of the equipment (including any incidental costs for hazardous materials).

Medical Waste and Disposal

Due to the liability risks related to biological and medical waste, the landlord may wish to require, at the tenant's expense, periodic inspections of the premises by an environmental specialist to ensure compliance with applicable environmental regulations. Often the landlord will allocate the disposal of medical and biological waste to the tenant, with certain prohibitions on the disposal of materials during certain hours or through certain methods (e.g., the sewer systems). The landlord will often also seek to allocate as much risk as possible to the tenant related to the generation and disposal of such waste and may even seek specific requirements related to storage, permitting, and handling of waste that exceed the ASC's obligations under law.

In addition, the landlord's attorney may seek to negotiate significant liability disclaimers and indemnifications related to the occurrence of a hazardous spill. In the event of such a spill, the landlord may also wish to be notified and to receive certain assurances that spills will be handled by an agreed-upon chemical or biological cleanup company in accordance with requirements applicable to one or both parties. The landlord should require that the tenant surrender the property free of all medical and biological waste and also ensure that the obligations related to cleanup survive the termination of the lease. L

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RESEARCH PATH: *Real Estate > Commercial Leasing > Lease Agreement > Practice Notes*

23. *See* Americans with Disabilities Act of 1990, as amended, ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (2008). 24. *See* 28 C.F.R. § 36.401, 570 (July 1, 2004).

LN Announces Launch of LexisNexis Rule of Law Foundation

In keeping with its longtime support of the rule of law around the world, LexisNexis on January 29 announced the establishment of the non-profit LexisNexis Rule of Law Foundation.

IN A STATEMENT, LEXISNEXIS LEGAL & PROFESSIONAL CEO Mike Walsh said that the foundation is "designed to help leading entities from legal, judicial, academic, NGO and other sectors advance one or more of the four rule of law components: equal treatment under the law, transparency of law, access to legal remedy, and independent judiciaries."

Walsh said that projects undertaken by the foundation will focus on a wide range of work in local, national, regional, and multiregional jurisdictions around the world.

Among the recent projects undertaken by LexisNexis in support of the rule of law are:

- Collaboration with the International Bar Association in London to create eyeWitness to Atrocities, a program that combines law and technology though use of a mobile camera app to help human rights advocates document and report evidence of human rights atrocities to authorities for presentation in court
- A partnership with the Law Society of England & Wales to support the Women in Leadership in Law Project by providing marketing expertise to disseminate and promote an international survey and facilitating roundtable discussions
- Participation of more than 36 employees in scanning and providing data cleanup of print versions of "Freedom in the World," the annual report produced by the human rights group Freedom House to allow for the creation of searchable PDFs

In addition to its work through the foundation, LexisNexis promotes the rule of law around the globe through its daily operations, products and services; the efforts of its employees; and collaboration with customers, governments, non-profits, and intergovernmental organizations. "Everything that we do as a commercial business advances the rule of law," Walsh said. "Publishing laws, news, delivering decisions, and enabling access to justice is at our core."

Additional information about the foundation is available at https://www.lexisnexisrolfoundation.org/.

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