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Chair's Column: Using Our Unique Gifts To Help Others

By John H McEniry IV, Fagron North America, Fairhope, AL

In looking back over past Chair’s Columns, I am (again) awestruck by the depth and personal insights offered by Alexandria, Hilary, Joyce, Bill, and the many great Chairs before them. One of my personal favorites, though, is the November 2016 Chair’s Column penned by Joyce Hall. In My Veteran, Joyce introduces us to her grandfather, who was both a proud veteran and the proud father of a veteran. Pawpe, as Joyce affectionately called him, possessed the discipline, work ethic, and love of family and country characteristic of the generations who survived two World Wars and the Great Depression. I would love to have met him.

The stories and lessons conveyed by Joyce bring back familiar and very fond memories of my own grandfather. He served in the U.S. Marine Corps as a dive-bomber pilot at Guadalcanal in 1942-43 and subsequently as the commanding officer of a squadron in the central Pacific. Following active military service, he practiced law at our family practice in Bessemer, AL and later wrote a book detailing his time in the south Pacific “with the thought that it would be of some interest to my grandchildren in their later years.” GraGra, which I affectionately called him (and which was the first “word” I ever spoke as a child), was a towering man, both in physical stature and character. His discipline, work ethic, and servant’s heart were qualities to which I will always aspire, but will never achieve.

To steal a word from Joyce, GraGra loved his family “fiercely.” Due to this fierce love and a mentality that his family would never encounter the same struggles that he faced in the early 1930s, GraGra was a driven provider. We did not have to rely on the VA for medical care. We could obtain professional assistance whenever we needed it. When GraGra was stricken with cancer in his later years, we were able to seek the best medical and palliative care. When I had a hard time processing his death, I was able to see somebody to help me work through it. In all, my family and I have never really wanted for anything. I took that comfort for granted as a child and young adult. In many ways, I still do.

Unfortunately, there are many who do not enjoy the same comforts and opportunities. Many active and retired service members rely on a perpetually understaffed and underfunded system to serve their medical needs. They deserve better. The same can be said for many civilians relying on federal- and state-funded medical care. Mental health and substance use disorders remain an epidemic for which limited progress is being made, particularly for individuals with limited resources. Many families facing a cancer diagnosis can barely get their minds or checkbooks around immediately necessary medical treatment, much less planning for the myriad legal issues which surround and follow such life-altering events. As lawyers, while we can’t use a scalpel or prescribe medications to address these issues, we are nevertheless in a unique position to use our education, experience, abilities, and resources to help individuals and families in need.

As you consider how and where to allocate your time, talents, and treasures in 2020, I invite you to join your colleagues in the Health Law Section to serve the public through the Section’s four Educational/Outreach Interest Groups – Cancer Legal Advocacy, Medical-Legal Partnerships, Military and Veterans Health Law, and Substance Use Disorders & Mental Health. A short
description of each Interest Group’s focus and efforts is set forth below. Through their passionate and dedicated leaders and members, these Interest Groups are making a substantial difference in communities across the country. Please join them in making a difference in your own community.

**Cancer Legal Advocacy Interest Group (formerly the Breast Cancer Initiatives Interest Group):** The Cancer Legal Advocacy IG provides cancer legal advocacy training to lawyers, resources for lawyers and consumers facing cancer, and education for consumers, attorneys and policymakers on the wide range of legal issues surrounding a diagnosis and treatment of cancer. The IG’s primary mission is to coordinate training sessions for attorneys and public servants interested in assisting cancer patients who need legal advice related to their diagnosis and treatment.

**Medical/Legal Partnerships Interest Group:** The Medical/Legal Partnerships (“MLPs”) IG develops and supports partnerships between physicians, social services, and attorneys at hospitals and other health care facilities to address issues that negatively affect individual health conditions. The IG provides education, support, resources and assists in connecting volunteers with MLP projects.

**Military and Veterans Health Law Interest Group:** The Military and Veterans Health Law IG is designed to lead and implement educational programming focused on protecting the legal rights of our service personnel, veterans, and their families. The IG provides training for attorneys counseling current and retired military regarding the legal issues related to their health care. The IG collaborates with the ABA’s Military Pro Bono Center and Veterans' Claims Assistance Network (VCAN) to provide legal assistance in eight Civil Law areas.

**Substance Use Disorders & Mental Health Interest Group:** The Substance Use Disorders and Mental Health IG promotes practices that support prevention, education, treatment, recovery and management of substance use disorders and mental health conditions. The IG works to expand access to and delivery of health care services at the state and federal levels, including the removal of legal barriers to successful addiction and mental health recovery. The IG examines the effects of substance use disorders and mental health conditions on society, the practice of law, and the nature of the American justice system.

In addition, the Health Law Section’s Program Support Fund encourages and supports attorney pro bono activities in communities across the United States. Through the generous contributions of Section members and others committed to supporting their communities, the Section is able to engage and support attorneys to serve individuals and families in need through the above-described programs. The Program Support Fund is a 501(c)(3) charitable fund, so a donation is tax-deductible to the fullest extent available under the law.

**Please consider contributing to the Program Support Fund at donate.americanbar.org/healthlaw.** If you have questions, please contact Health Law Section Associate Director Carol Simmons at carol.simmons@americanbar.org.

I wish you and yours a safe and happy holiday season.
Jay McEniry
Chair
CMS Greatly Expands Its Authority to Deny and Revoke Providers’ and Suppliers’ Medicare Enrollment

By Jessica L. Gustafson, Esq. and Adrienne Dresevic, Esq., The Health Law Partners, P.C., Farmington Hills, MI

I. Introduction

On September 10, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a Final Rule addressing “Medicare, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process” (Final Rule). The Final Rule became effective November 4, 2019. It implements statutory requirements that providers and suppliers enrolling or already enrolled with Medicare, Medicaid and the Children’s Health Insurance Program (CHIP) disclose certain current and prior affiliations with other healthcare providers and suppliers with program integrity concerns. The Final Rule also expands CMS’s authority to deny or revoke a provider’s or supplier’s enrollment. CMS views its authority to grant, deny and revoke providers’ and suppliers’ enrollment as an essential program integrity tool to prevent against fraud, waste and abuse. In the Final Rule, CMS describes its expanded denial and revocation authority as necessary to enable “CMS to take action against unqualified and potentially fraudulent entities and individuals.” However, in addition to “unqualified and potentially fraudulent entities and individuals,” at times even well-meaning healthcare providers and suppliers have faced revocations for unknowing and unintentional lack of compliance with enrollment regulations. Given the high stakes for compliance outlined in the Final Rule, now, more than ever, it is essential for healthcare providers, suppliers and their legal counsel to familiarize themselves with the regulations to ensure compliance.

II. Background
Section 1866(j) of the Social Security Act (Act)\(^5\) was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.\(^6\) This section of the law directed the Secretary of the Department of Health and Human Services (HHS) to adopt a regulatory process for Medicare enrollment. On April 21, 2006, CMS published a final rule implementing the MMA’s provisions related to enrollment, setting forth the requirements for providers and suppliers to obtain and maintain Medicare enrollment (2006 Final Rule).\(^7\) The requirements are codified in 42 C.F.R. Part 424, Subpart P. The intent of the 2006 Final Rule was “to protect beneficiaries and the Medicare Trust Funds by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or billing the Medicare program or its beneficiaries.”\(^8\) Subsequently, the regulations have been updated from time to time to address payment safeguard issues.\(^9\)

The enrollment regulations require that, in order to enroll in the Medicare program and obtain billing privileges, providers and suppliers must submit an applicable Medicare enrollment application (\textit{i.e.}, the applicable version of the CMS-855).\(^10\) The application may be submitted on paper or electronically via the Provider Enrollment, Chain and Ownership System (PECOS).\(^11\) Data collected at the time of Medicare enrollment includes, but is not limited to, the following provider or supplier information: (1) identifying information; (2) licensure data; (3) practice locations; (4) any adverse actions taken against the provider or supplier; and (5) information regarding the provider’s or supplier’s owners and managing individuals and organizations (including any adverse actions taken against them).\(^12\) Enrollment information must be submitted to CMS upon the following occurrences: initial enrollment; if there is a change in ownership; if there is a change of information; and revalidation and/or reactivation.\(^13\)

\textbf{III. Affiliations and Disclosable Events}
Section 1866(j)(5) of the Act\textsuperscript{14} was added by Section 6401(a)(3) of the Patient Protection and Affordable Care Act, and requires that a provider or supplier submitting an enrollment application or enrollment revalidation application for Medicare, Medicaid, or CHIP disclose any current or prior direct or indirect affiliation with a provider or supplier that:

- Has an uncollected debt; or
- Has been or is subject to a payment suspension under a federal healthcare program; or
- Has been excluded from Medicare, Medicaid or CHIP; or
- Has had its billing privileges denied or revoked.

If the Secretary determines that any such affiliation poses an undue risk of fraud, waste or abuse, the provider’s or supplier’s enrollment application may be denied.\textsuperscript{15} The Final Rule codifies these statutory provisions.\textsuperscript{16}

A. Affiliation

The Final Rule defines the term “affiliation” as part of 42 C.F.R. § 424.502, as follows:

(1) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
(2) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.\textsuperscript{17}
(3) An interest in which an organization or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization.
(4) An interest in which an individual is acting as an officer or director of a corporation.
(5) Any reassignment relationship under § 424.80.

Prior to the effective date of the Final Rule, providers and suppliers already were required to disclose the relationships described above. Interests described in items (1) through (4) above are consistent with the definitions of “owner,”\textsuperscript{18} “managing employee”\textsuperscript{19} and “ownership or control interest,”\textsuperscript{20} which were, and remain, required to be disclosed on all of the CMS-855 enrollment forms. With respect to item (5), reassignment relationships were, and remain,
required to be disclosed on CMS-855R, which is the form completed when a provider or supplier is reassigning, or terminating a prior reassignment of, his/her/its right to bill the Medicare program and receive Medicare payments for services rendered to Medicare beneficiaries.\textsuperscript{21}

In order to reduce provider and supplier burden associated with identifying affiliated interests, CMS imposed a five year lookback period for reporting affiliations.\textsuperscript{22} Calculated from the date of submission of an enrollment application, providers and suppliers must disclose any affiliation relationship that occurred within the preceding five years (even if such relationship has ended), if the affiliated provider or supplier experienced a disclosable event.\textsuperscript{23}

**B. Disclosable Event**

The Final Rule defines “disclosable event” in 42 C.F.R. §424.502 as follows:

*Disclosable event* means, for purposes of §424.519,\textsuperscript{24} any of the following:

1. Currently has an uncollected debt to Medicare, Medicaid, or CHIP, regardless of—
   - (i) The amount of the debt;\textsuperscript{25}
   - (ii) Whether the debt is currently being repaid (for example, as part of a repayment plan); or
   - (iii) Whether the debt is currently being appealed;
2. Has been or is subject to a payment suspension under a federal health care program (as that latter term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed;
3. Has been or is excluded by the [Department of Health and Human Services Office of Inspector General] OIG from participation in Medicare, Medicaid, or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed; or
4. Has had its Medicare, Medicaid, or CHIP enrollment denied, revoked or terminated, regardless of—
   - (i) The reason for the denial, revocation or termination;\textsuperscript{26}
   - (ii) Whether the denial, revocation or termination is currently being appealed; or
   - (iii) When the denial, revocation or termination occurred or was imposed.

Because providers and suppliers already were required to disclose affiliation relationships as part of the CMS-855 enrollment application(s), it may not prove overly burdensome for providers or suppliers to comply with the Final Rule to identify their affiliation relationships.
However, researching and reporting the affiliated entities’ disclosable events may be another story. Consider, for example, a large health system with many reassignment relationships. Under the Final Rule, the health system must research and submit data to CMS involving any disclosable event of any provider or supplier with a reassignment relationship with the health system. In the Final Rule, CMS acknowledges this “potentially sizeable burden,” but ultimately chose to retain reassignment relationships within the definition of affiliation and require disclosure of such affiliated entities’ disclosable events. It is important to remember that a physician or other practitioner may have multiple reassignments with various entities (such as physician group practices) enrolled under the CMS-855B, and thus, under the Final Rule, one entity could have its application denied or its billing privileges revoked because of some issue involving a reassigning practitioner that arose in connection with some other, unrelated entity to which the practitioner also reassigned benefits.

Importantly, the Final Rule does not establish a lookback period for disclosable events. Therefore, if a current affiliated entity of a provider or supplier, or if a prior affiliated entity of a provider or supplier within the preceding five years, experienced a disclosable event at any time, this must be reported to CMS. If such disclosable events are not reported, CMS may deny or revoke a provider’s or supplier’s Medicare enrollment if it determines that the provider or supplier knew or should reasonably have known about the disclosable event.

C. Disclosure

When disclosure is required, a provider or supplier must disclose to CMS the following data on the applicable CMS-855 enrollment form:

- General identifying information about the affiliated entity;
- A description of the affiliated entity’s disclosable event;
• Information regarding the nature and scope of the relationship between the provider or supplier and its affiliate;

• Information regarding the length of the relationship between the provider or supplier and the affiliated entity; and if the affiliation relationship ended, the reasons for same.  

In the Final Rule, CMS does not detail its expectations regarding the extent of research a provider or supplier must undertake in order to determine whether an affiliated entity has a history of a disclosable event. Instead, CMS imposes a “reasonableness” standard. Pursuant to 42 C.F.R. § 424.519 (e), CMS may deny or revoke a provider’s or supplier’s Medicare enrollment if it “knew or should reasonably have known” information concerning a disclosable event of an affiliate, and it did not disclose such event to CMS. Consistent with longstanding practice, providers and suppliers are not afforded pre-revocation due process protection.

The Final Rule lacks specificity regarding the “reasonableness standard.” In the commentary to the Final Rule, CMS states its intent to issue sub-regulatory guidance in the future that will clarify its “expectations regarding the level of effort that is required in securing the relevant affiliation information.” Until such sub-regulatory guidance is issued outlining with specificity CMS’s expectations, providers and suppliers must make good faith efforts to secure information concerning an affiliated entity’s disclosable events. In the commentary to the Final Rule, CMS cautions providers and suppliers that, “we strongly reemphasize … actual knowledge without any attempt to research affiliation data” is insufficient to demonstrate compliance. CMS notes that the required amount of research might include searching publicly available databases, reviewing internal records, and contacting the affiliated entities. Importantly, researching publicly-available databases alone also will be insufficient to comply, because information surrounding all disclosable events is not publicly available. For example, there is no publicly available database which lists providers or suppliers with existing Medicare
debts. Therefore, providers and suppliers will be reliant on their affiliates to provide accurate and complete information related to disclosable events.

Until CMS issues its sub-regulatory guidance providing greater clarity as to its expectations, at a minimum providers and suppliers should document all attempts to obtain such information from their affiliates. If CMS were to identify a non-disclosed, disclosable event of an affiliation of a provider or supplier and deny or revoke a provider’s or supplier’s Medicare enrollment as a result, such documentation could be used in the appeals process to establish that the provider or supplier did not know or have reason to know of the event.

D. Undue Risk

After receiving information concerning a provider’s or supplier’s affiliates’ disclosable events, CMS will determine whether any of the affiliations poses an undue risk of fraud, waste or abuse. In making this determination, CMS will consider “(1) the length and period of the affiliation; (2) the nature and extent of the affiliation; and (3) the type of disclosable event and when it occurred.” However, in the Final Rule CMS declines to set forth specific thresholds that would establish undue risk, stating, “we must retain the flexibility to deal with the situation(s) on a case-by-case basis.”

E. Phased-In Compliance

There are approximately 1.7 million providers and suppliers enrolled in Medicare, Medicaid and/or CHIP. For CMS to secure affiliation data from all providers and suppliers is a monumental undertaking. Further, as noted above, CMS has acknowledged the administrative burdens attached to compliance with the Final Rule from the provider and supplier perspective. Accordingly, at least “for now,” not all providers and suppliers will be required to research and disclose affiliation data. Rather:
• For Medicare, (1) after CMS has updated its CMS-855 enrollment application forms to include an affiliation disclosure section; and (2) if CMS identifies at least one affiliation involving a disclosable event and requests that a provider or supplier report any and all affiliations; then (3) upon initial enrollment or revalidation (as applicable) the provider or supplier will be required to report all affiliations that have had a disclosable event.

In the Final Rule, CMS seeks public comment regarding potential approaches for securing affiliation data from all providers and suppliers. Comments were due November 4, 2019.

• For Medicaid and CHIP, as with the Medicare phase-in approach, reporting to Medicaid and CHIP will not be required until after a state has revised its relevant enrollment applications to include an affiliation disclosure section. Only providers and suppliers that are not enrolled in Medicare will be required to report to the state any affiliations that have a disclosable event. Under the Final Rule, states may choose one of two options for the implementation of the affiliation disclosure requirement. Once chosen, states are prohibited from changing their selections until after CMS engages in additional rulemaking.

  o **Option One:** All newly enrolling or revalidating Medicaid and/or CHIP providers must disclose data related to affiliations with disclosable events.

  o **Option Two:** Only after a state requests that a provider or supplier disclose an affiliation with disclosable events must the provider or supplier disclose data. The disclosed data must not be limited only to data involving the affiliate identified by the state; instead, the provider or supplier will be required to submit data regarding all affiliations with disclosable events.

### IV. Implications

There is no question that CMS has granted itself significant flexibility to determine whether an affiliation poses an undue risk of fraud, waste or abuse, which flexibility has the potential for arbitrary and capricious actions. In the Final Rule, CMS attempts to assuage providers’ and suppliers’ concerns related to perceived unfettered discretion through repeated assertions that it will make determinations in a careful manner. For example:

> While we acknowledge that some affiliations may pose greater risks than others (and some may pose little, if any, risk), it is possible that even certain ‘‘distant’’ affiliations could, depending on the particular facts of the case, threaten the integrity of Medicare, Medicaid, or CHIP. We consequently must retain the discretion to review each case on its own merits by carefully considering the factors outlined in § 424.519(f)…”
The disclosure requirement is entirely separate from any undue risk finding. Indeed, CMS must first carefully review and analyze all disclosed affiliations before determining whether the undue risk standard…has been met; CMS will, in every case, act with caution and prudence and caution when determining whether an undue risk of fraud, waste, or abuse exists…  

[W]e stress that we will only take denial or revocation action pursuant to § 424.519(e) after careful consideration of the facts and circumstances and not as a matter of course…

As stated previously, we will exercise our denial or revocation authority under § 424.519(f) carefully. However, we do not believe that the disclosable event must have involved intentional fraud or misconduct for an affiliation to present an undue risk. Other types of affiliations involving behavior that does not contain such elements can endanger federal health care programs. Again, we will carefully consider the circumstances of the disclosable event in making our undue risk determinations…

Providers and suppliers will soon learn how judicious CMS will be with its denial and revocation authority under the new regulation. Providers, suppliers, and their legal counsel are well-advised to closely review the Final Rule and keep close watch for forthcoming sub-regulatory guidance.

V. **Provisions Affecting Medicare Only**

The Final Rule also expands CMS’s denial and revocation authority under 42 C.F.R. §§ 424.530 and 424.535. There are 10 main provisions of the Final Rule related to Medicare enrollment, which are discussed in detail below: (1) Revoked under Different Name, Identifier or Business Identity; (2) Non-Compliant Practice Location; (3) Improper Ordering, Certifying, Referring or Prescribing; (4) Referral of Debt to the United States Department of Treasury; (5) Failure to Report; (6) Payment Suspensions; (7) Other Federal Program Termination; (8) Extension of Revocation, (9) Voluntary Termination Pending Revocation; and (10) Extension of Reenrollment Bar and Reapplication Period.

A. **Revoked under Different Name, Identifier or Business Identity**
CMS and the OIG have identified numerous scenarios in which a provider or supplier has its Medicare enrollment revoked, and prior to the expiration of a reenrollment bar, the provider or supplier opens a new organization to replace the revoked one. In such situations, family members or other individuals may pose or “front” as owners or managers on the entity, when in truth it is the revoked provider or supplier that is operating and profiting from the business.57

To address these concerns, the Final Rule revises 42 C.F.R. §§ 424.530 (a) (12) and 424.535 (a) (18) to allow CMS to deny or revoke a provider’s or supplier’s Medicare enrollment if it determines that the provider or supplier is currently revoked under a different name, numerical identifier or business identity.58 In making such a determination, CMS will consider the following:

- The owners and managing employees and organizations, even if such persons or entities are not identified on the CMS-855 enrollment application;
- Location (e.g., same city or county);
- Provider or supplier type;
- Business structure; and
- Any other evidence of similarity between the two parties.59

CMS reserves the right to invoke its denial or revocation authority even if the two parties have different owners, locations or business structures, if other evidence suggests that a provider or supplier is attempting to evade a reenrollment bar.60

**B. Non-Compliant Practice Location**

Providers and suppliers with multiple practice locations, which may be separately enrolled with Medicare, raise additional program integrity considerations. Consider the following illustration:
[A]ssume that a DMEPOS supplier has four separately enrolled locations. The supplier shifts one of its locations without notifying Medicare, and the new site is a false storefront. The supplier furnishes no items from this location, but it submits and bills for DME allegedly provided from this site. Under our proposal, CMS could revoke this location as well as the three other sites. Even if the other sites had different numerical identifiers, legal business names, or ownership, we could take action against them if there is evidence to suggest that they are effectively under the control of similar parties. This is to ensure that providers and suppliers do not attempt to circumvent § 424.535 (a) (20) by opening locations under different identities or with different “front men” (such as family members).61

Prior to the effective date of the Final Rule, CMS did not have this authority.

To address situations where a provider or supplier bills for services or supplies rendered from locations that are non-compliant with Medicare enrollment requirements, the Final Rule adopts a new 42 C.F.R. § 424.535 (a) (20), expanding CMS’s revocation authority. Under this provision, CMS may revoke a provider’s or supplier’s Medicare enrollment(s), including all of the provider’s or supplier’s locations, if it “billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements.”62

The language contained in 42 C.F.R. § 424.535 (a) (20) is permissive; CMS may revoke any or all of provider’s or supplier’s Medicare enrollments if it determines that one practice location is noncompliant with Medicare’s requirements. In making such a determination, CMS will consider the following factors:

- The type of non-compliance (e.g., whether the location constitutes a false storefront, is non-operational, etc.);

- The number of locations involved;

- The provider’s or supplier’s history of final adverse action(s) or Medicare or Medicaid payment suspensions;

- Whether allowing the other locations to remain enrolled in Medicare places the Medicare Trust Funds at risk;
• The length of time of non-compliance;
• The amount billed from the non-compliant location; and
• Any other evidence CMS deems relevant.

C. Improper Ordering, Certifying, Referring or Prescribing

Under 42 C.F.R. § 424.535 (a) (8) (ii) (in place prior to implementation of the Final Rule), CMS may revoke a provider’s or supplier’s Medicare privileges if the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In addition, under 42 C.F.R. § 424.535 (a) (14) (also in place prior to implementation of the Final Rule), CMS may revoke a physician’s or eligible professional’s Medicare billing privileges if he or she has demonstrated a pattern or practice of prescribing Part D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. However, prior to implementation of the Final Rule, there was no authority for CMS to revoke a provider’s or supplier’s Medicare privileges for ordering, certifying, referring or prescribing Medicare Part A or B items or services that fail to meet Medicare requirements.63

Therefore, the Final Rule adopts a new 42 C.F.R. § 424.535 (a) (21), which grants CMS the authority to revoke a physician’s or eligible professional’s enrollment if he or she “has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.” To determine whether a pattern or practice constitutes improper behavior, CMS will consider the following factors:

• Whether the physician’s or eligible professional’s order contained a diagnosis to support coverage for the services or supplies at issue;
• Whether it was impossible for an evaluation to have taken place to support the order at issue (e.g., if the patient was deceased);

• Whether the physician or eligible professional had been subject to disciplinary action(s) taken by a licensing body or the medical board for the state(s) in which the physician or eligible professional practiced;

• Whether the physician or eligible professional had a history of final adverse actions;

• The duration of the pattern or practice at issue;

• How long the physician or eligible practitioner had been enrolled in Medicare;

• Whether the physician or eligible professional had ever been a defendant in a malpractice action related to his or her ordering behaviors that resulted in a final judgment against the physician or eligible professional or where the physician or eligible professional paid a settlement to the plaintiffs;

• Whether any state Medicaid program or any other public or private health insurance program had taken action against the physician’s or eligible professional’s ability to practice medicine and the reasons for same; and

• Any other information CMS deems to be relevant.64

D. Referral of Debt to the United States Department of Treasury

Pursuant to the Debt Collection Improvement Act of 1996 (Public Law 104-134, April 26, 1996), federal agencies must refer eligible65 delinquent debts to the United States Department of Treasury designated Debt Collection Center for cross-servicing and offset.66 Eligible debts that are delinquent over 120 days are referred for cross-servicing and offset.67 Prior to referring debts to the Department of Treasury, CMS attempts to recoup the debt under the procedures set forth in Chapter 4 of the Medicare Financial Management Manual (such procedures include recoupment by withholding payments and allowing a provider or supplier to enter into an extended repayment schedule).68

CMS believes that if a provider or supplier has a delinquent debt that is eligible for referral to the Department of Treasury, this illustrates that the provider or supplier is unwilling to
repay the debt, justifying revocation of the provider’s or supplier’s Medicare enrollment. Therefore, the Final Rule creates a new 42 C.F.R. § 424.535 (a) (17), which serves to implement Section 1866(j)(5) of the Act and authorizes CMS to revoke a provider’s or supplier’s enrollment if he/she/it has an existing debt that is appropriately referred to the Department of Treasury. In determining whether revocation is appropriate, CMS will consider the following factors:

- The reasons the debt has not been fully repaid;
- Whether the provider or supplier had tried to repay the debt;
- Whether the provider or supplier responded to CMS’ attempts to collect the debt;
- Whether the provider or supplier had a history of final adverse actions or Medicare or Medicaid payment suspensions;
- The amount of the debt; and
- Any other information that CMS deems to be relevant.69

E. Failure to Report

Prior to implementation of the Final Rule, 42 C.F.R. § 424.535 (a) (9) authorized CMS to revoke the Medicare enrollment of a physician, non-physician practitioner, physician group, or non-physician practitioner group for failure to comply with § 424.516 (d) (1) (ii) or (iii) (i.e., for failure to report a change in practice location or final adverse action within 30 days). In the Final Rule, CMS expands 42 C.F.R. § 424.535 (a) (9) to apply to all of the reporting requirements in § 424.516 (d), and not only those codified in subsections (d) (1) (ii) and (iii).70 This means that CMS may revoke the Medicare enrollment of a physician, non-physician practitioner, physician group, or non-physician practitioner group for failing to report a change in ownership, final adverse action, or practice location change within 30 days and all other changes in enrollment information within 90 days.71 In addition, the Final Rule expands the applicability of 42 C.F.R.
§ 424.535 (a) (9) to independent diagnostic testing facilities (IDTFs) and DMEPOS suppliers.\textsuperscript{72} In determining whether revocation is appropriate, CMS will consider whether the data was eventually reported; when the data was reported (if it was reported); the materiality of the data; and any other information CMS deems to be relevant.\textsuperscript{73}

\textbf{F. Payment Suspensions}

Prior to the effective date of the Final Rule, 42 C.F.R. § 424.530 (a) (7) authorized CMS to deny a provider’s or supplier’s Medicare enrollment application if a current owner, physician, or non-physician practitioner had been placed under a Medicare suspension. The Final Rule implements Section 1866(j)(5) of the Act and expands the applicability of 42 C.F.R. § 424.530 (a) (7) to all provider and supplier types, and to Medicare and Medicaid payment suspensions imposed on any owner or any managing employee or managing organization of the provider or supplier (under any current or former name, numerical identifier, or business identity).\textsuperscript{74} The Final Rule also authorizes CMS to impose a Medicare payment suspension if a provider or supplier is subject to a state Medicaid payment suspension.\textsuperscript{75}

\textbf{G. Other Federal Program Termination}

In the Final Rule, CMS expands its denial and revocation authority involving state Medicaid program terminations and licensure actions. CMS expressed concern that a provider’s or supplier’s behavior in a state Medicaid program could be easily replicated in the Medicare program, creating program integrity risk.\textsuperscript{76}

Under new 42 C.F.R. § 424.530 (a) (14) (i), CMS may deny a provider’s or supplier’s Medicare enrollment if:

The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other federal health care program, or the provider’s or supplier’s license is currently
revoked or suspended in the State other than that in which the provider or supplier is enrolling.77

These provisions apply even if an appeal is pending.78

Under 42 C.F.R. § 424.535 (a) (12), CMS is authorized to revoke a provider’s or supplier’s Medicare enrollment if a state Medicaid agency terminates the provider’s or supplier’s state Medicaid enrollment.79 Under the Final Rule, CMS’s authority to revoke a provider’s or supplier’s Medicare enrollment is broadened to include situations where the provider or supplier is terminated or revoked from participation in any other federal healthcare program.80 CMS may not revoke a provider’s or supplier’s Medicare enrollment under this regulation unless and until all applicable appeal rights are exhausted.81

In determining whether to deny or revoke a provider’s or supplier’s Medicare enrollment under 42 C.F.R. § 424.530 (a) (14) or 42 C.F.R. § 424.535 (a) (12), CMS will evaluate the following:

- The reason(s) for the termination or revocation.
- Whether the provider or supplier:
  ++ Is currently terminated, revoked, or otherwise barred from more than one program (for example, more than one state’s Medicaid program); or
  ++ Has been subject to any other sanctions during its participation in other programs.
- Any other information that [CMS] deem[s] relevant to [its] determination.82

H. Extension of Revocation

It is a goal of CMS to ensure that if a provider or supplier is revoked for engaging in improper conduct, that provider or supplier may not remain in the Medicare program in any capacity. Accordingly, in the Final Rule, CMS adds a new regulation, codified at 42 C.F.R. § 424.535 (i), to permit CMS to revoke all of a provider’s or supplier’s Medicare enrollments,
including those under different names, numerical identifiers, or business identities, and including
different provider and supplier types, if the provider or supplier faces Medicare revocation
pursuant to 42 C.F.R. § 424.535 (a). In making this determination, CMS will consider the
following factors:

• The facts of the case and why the provider or supplier faced revocation;
• Whether the provider or supplier had a history of other final adverse actions;
• The number and type of other enrollments; and
• Any other information CMS deems to be relevant.

I. Voluntary Termination Pending Revocation

Prior to the implementation of the Final Rule, CMS observed scenarios in which a
provider or supplier failed to comply with Medicare’s enrollment requirements and then
voluntarily terminated his/her/its Medicare enrollment to avoid a potential revocation of that
provider’s or supplier’s Medicare enrollment and corresponding reenrollment bar. CMS views
such actions as dishonest and a circumvention of the intent of the Medicare enrollment
requirements. The Final Rule addresses this program vulnerability.

Under the Final Rule, new 42 C.F.R. § 424.535 (j) (1) permits CMS to revoke a
provider’s or supplier’s Medicare enrollment if it determines the provider or supplier voluntarily
terminated its Medicare enrollment to avoid a revocation. In making the determination, CMS
will consider the following:

• Whether the provider or supplier knew or should have known that it was, or would
  become, out of compliance with Medicare enrollment requirements; and therefore
  whether the provider or supplier knew or should have known that it may be subject to
  revocation of its Medicare enrollment;

• Whether the provider or supplier voluntarily terminated its Medicare enrollment to
circumvent such revocation; and
Any other information CMS deems relevant.

J. Reenrollment Bar and Reapplication Period

In addition to expanding CMS’s denial and revocation authority, the Final Rule also significantly extends the maximum reenrollment bar following revocation of a provider’s or supplier’s Medicare enrollment. Prior to the Final Rule’s implementation, the maximum reenrollment bar following a revocation of a provider’s or supplier’s Medicare enrollment was three years.88 The Final Rule revised 42 C.F.R. § 424.535 (c) as follows:

(1) After a provider or supplier has had their [sic] enrollment revoked, they [sic] are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar –

(i) Begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years (except for the situation described in paragraphs (c) (2) and (3) of this section), depending on the severity of the basis for revocation.

(ii) Does not apply in the event a revocation of Medicare enrollment is imposed under paragraph (a) (1) of this section based on a provider’s or supplier’s failure to respond timely to a revalidation request or other request for information.

(2) (i) CMS may add up to 3 more years to the provider’s or supplier’s reenrollment bar (even if such period exceeds the 10-year period identified in paragraph (c) (1) of this section) if it determines that the provider or supplier is attempting to circumvent its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier or business identity…89

(3) CMS may impose a reenrollment bar of up to 20 years on a provider or supplier if the provider or supplier is being revoked from Medicare for the second time. In determining the length of the reenrollment bar under this paragraph (c) (3), CMS considers the following factors:

(i) The reasons for the revocations.

(ii) The length of time between the revocations.
(iii) Whether the provider or supplier has any history of final adverse actions (other than revocations) or Medicare or Medicaid payment suspensions.

(iv) Any other information that CMS deems relevant to its determination.

(4) A reenrollment bar applies to a provider or supplier under any of its current, former or future names, numerical identifiers or business identities.90

In reply to commenters’ concerns that the expanded reenrollment periods were “excessive and overly punitive,” CMS responds that such maximums are necessary, first, to ensure that abusive providers and suppliers are kept out of the Medicare program, and second, as a deterrent to others from engaging in abusive conduct.91 Declining to specify reenrollment bar lengths for particular acts, CMS provides the vague assurance that 10-year reenrollment bars would “generally be restricted to serious behavior.”92 CMS also cautions that “serious misconduct” could take place without a criminal conviction.93 Time will tell what actions CMS will deem to constitute “serious misconduct.” At times, CMS has viewed administrative oversights to constitute actions serious enough to invoke the maximum reenrollment bar. For example, prior to implementation of the Final Rule, CMS routinely doled out three-year reenrollment bars for a provider’s or supplier’s failure to report a change of information within the required timeframe(s). Again, it is important to remember that CMS does not afford a due process right to respond to a proposed revocation.

The Final Rule also implements new 42 C.F.R. § 424.530 (f), prohibiting a prospective provider or supplier from enrolling in Medicare for up to three years if the prospective provider’s or supplier’s enrollment application is denied because the applicant submitted false or misleading information on, or if it omitted information from, its CMS-855 application. In determining a reapplication bar’s length, CMS will consider:

- The materiality of the information;
• The prospective provider’s or supplier’s intent (i.e., whether it purposely submitted false or misleading information or purposely withheld information);

• Whether the prospective provider or supplier has a history of final adverse actions; and

• Any other information CMS deems relevant.\textsuperscript{94}

VI. Conclusion

The illustrations provided within the Final Rule highlight CMS’s concerns related to the behaviors of certain providers and suppliers engaging in acts that jeopardize the integrity of the Medicare Trust Funds (e.g., sham store fronts, providers and suppliers with clear program integrity issues attempting to circumnavigate CMS’s authority to revoke their billing privileges and impose re-enrollment bars by voluntarily terminating their Medicare enrollments prior to revocation, etc.). It is laudable to address these program vulnerabilities. Despite CMS’s statements that it will carefully consider all relevant facts and circumstances prior to denying or revoking a provider’s or supplier’s Medicare enrollment, there have been occasions where providers and suppliers have been subject to revocation of their billing privileges for inadvertent administrative oversights. Given CMS’s expanded program integrity authority, the stakes have never been higher for compliance. Attorneys representing providers and suppliers must be more diligent than ever in helping clients ensure compliance with the Medicare enrollment regulations.

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The Final Rule adds a new 42 C.F.R. § 424.519 Disclosure of Affiliations:

(a) Definitions. For purposes of this section only, the following terms apply to the definition of disclosable event in § 424.502:

(1) “Uncollected debt” only applies to the following:

(i) Medicare, Medicaid, or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier.

(ii) Civil money penalties imposed under this title.

(iii) Assessments imposed under this title.

(2) “Revoked,” “Revocation,” “Terminated,” and “Termination” include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid, or CHIP enrollment to avoid a potential revocation or termination.

(b) General. Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms “owner” and “managing employee” as defined in §424.502) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in §424.502). CMS will request such disclosures when it has determined that the initially enrolling or revalidating provider or supplier may have at least one such affiliation.

(c) Information. The provider or supplier must disclose the following information about each reported affiliation:

(1) General identifying data about the affiliated provider or supplier. This includes the following:

(i) Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual).

(ii) “Doing business as” name (if applicable).

(iii) Tax identification number.

(iv) NPI.
(2) Reason for disclosing the affiliated provider or supplier.

(3) Specific data regarding the affiliation relationship, including the following:

   (i) Length of the relationship.

   (ii) Type of relationship.

   (iii) Degree of affiliation.

(4) If the affiliation has ended, the reason for the termination.

(d) **Mechanism.** The information required to be disclosed under paragraphs (b) and (c) of this section must be furnished to CMS or its contractors via the Form CMS-855 application (paper or the internet-based PECOS enrollment process).

(e) **Denial or revocation.** The failure of the provider or supplier to fully and completely disclose the information specified in paragraphs (b) and (c) of this section when the provider or supplier knew or should reasonably have known of this information may result in either of the following:

   (1) The denial of the provider's or supplier's initial enrollment application under §424.530 (a) (1) and, if applicable, §424.530 (a) (4).

   (2) The revocation of the provider's or supplier's Medicare enrollment under §424.535 (a) (1) and, if applicable, §424.535 (a) (4).

(f) **Undue risk.** Upon receiving the information described in paragraphs (b) and (c) of this section, CMS determines whether any of the disclosed affiliations poses an undue risk of fraud, waste, or abuse by considering the following factors:

   (1) The duration of the affiliation.

   (2) Whether the affiliation still exists and, if not, how long ago it ended.

   (3) The degree and extent of the affiliation.

   (4) If applicable, the reason for the termination of the affiliation.

   (5) Regarding the affiliated provider's or supplier's disclosable event under paragraph (b) of this section:

      (i) The type of disclosable event.
(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event is an uncollected debt:

(A) The amount of the debt.

(B) Whether the affiliated provider or supplier is repaying the debt.

(C) To whom the debt is owed.

(v) If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.

(6) Any other evidence that CMS deems relevant to its determination.

(g) Determination of undue risk. A determination by CMS that a particular affiliation poses an undue risk of fraud, waste, or abuse will result in, as applicable, the denial of the provider's or supplier's initial enrollment application under §424.530 (a) (13) or the revocation of the provider's or supplier's Medicare enrollment under §424.535 (a) (19).

(h) Duplicate data. A provider or supplier is not required to report affiliation data in that portion of the Form CMS-855 application that collects affiliation information if the same data is being reported in the “owning or managing control” (or its successor) section of the Form CMS-855 application.

(i) Undisclosed affiliations. CMS may apply §424.530 (a) (13) or §424.535 (a) (19) to situations where a disclosable affiliation (as described in §424.519 (b) and (c)) poses an undue risk of fraud, waste or abuse, but the provider or supplier has not yet reported or is not required at that time to report the affiliation to CMS.
APPENDIX B

42 C.F.R. § 424.530 sets forth the reasons that CMS may deny a prospective provider’s or supplier’s enrollment in the Medicare program. As revised, 42 C.F.R. § 424.530 Denial of enrollment in the Medicare program states the following (the Final Rule’s revisions/additions are struck through and underlined, respectively):

(a) Reasons for denial. CMS may deny a provider’s or supplier’s enrollment in the Medicare program for the following reasons:

(1) Noncompliance. The provider or supplier is determined to not be in compliance with the enrollment requirements in this subpart P or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

(2) Provider or supplier conduct. A provider, supplier, an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application, in accordance with section 1862(e)(1) of the Act, is—

(i) Excluded from the Medicare, Medicaid and any other Federal health care programs, as defined in §1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(3) Felonies. The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

(i) Offenses include, but are not limited in scope or severity to—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the
individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(4) **False or misleading information.** The provider or supplier has submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.)

(5) **On-site review.** Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or

(ii) Otherwise fails to satisfy any Medicare enrollment requirement.

(6) **Medicare debt.**

(i) The enrolling provider, supplier, or owner thereof (as defined in § 424.502), has an existing Medicare debt.

(ii) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof was previously the owner (as defined in § 424.502) of a provider or supplier that had a Medicare debt that existed when the latter’s enrollment was voluntarily terminated, involuntarily terminated, or revoked, and all of the following criteria are met:
(A) The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier’s voluntary termination, involuntary termination or revocation.

(B) The Medicare debt has not been fully repaid.

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse. In making this determination, CMS considers the following factors:

(1) The amount of the Medicare debt.

(2) The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.

(3) The percentage of the enrolling provider, supplier, or owner’s ownership of the prior entity.

(4) Whether the Medicare debt is currently being appealed.

(5) Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred.

(iii) A denial of Medicare enrollment under this paragraph (a) (6) can be avoided if the enrolling provider, supplier, or owner thereof does either of the following:

(A) Satisfies the criteria set forth in § 401.607; and

(B) Agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt.

(B) Repays the debt in full.

(7) **Payment suspension.** The current owner (as defined in § 424.502), physician or nonphysician practitioner has been placed under a Medicare payment suspension as defined in § 405.370 through § 405.372 of this subchapter.
(i) The provider or supplier, or any owning or managing employee or organization of the provider or supplier, is currently under a Medicare or Medicaid payment suspension as defined in §§ 405.370 through 405.372 or in § 455.23 of this chapter.

(ii) CMS may apply the provision in this paragraph (a) (7) to the provider or supplier under any of the provider’s supplier’s or owning or managing employee’s or organization’s current or former names, numerical identifiers, or business entities or to any of its existing enrollments.

(iii) In determining whether a denial is appropriate, CMS considers the following factors:

   (A) The specific behavior in question.

   (B) Whether the provider or supplier is the subject of other similar investigations.

   (C) Any other information that CMS deems relevant to its determination.

(8) Initial Reserve Operating Funds.

   (i) CMS or its designated Medicare contractor may deny Medicare billing privileges if, within 30 days of a CMS or Medicare contractor request, a home health agency (HHA) cannot furnish supporting documentation which verifies that the HHA meets the initial reserve operating funds requirement found in § 489.28(a) of this title.

   (ii) CMS may deny Medicare billing privileges upon an HHA applicant's failure to satisfy the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(9) Application fee/hardship exception. An institutional provider's or supplier's hardship exception request is not granted, and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved.

(10) Temporary moratorium. A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.

(11) Prescribing authority.
A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked; or

The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

(12) **Revoked under different name, numerical identifier or business identity.** The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In determining whether a provider or supplier is a currently revoked provider or supplier under a different name, numerical identifier or business entity, CMS investigates the degree of commonality by considering the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 application).

(ii) Geographic location.

(iii) Provider or supplier type.

(iv) Business structure.

(v) Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumnavigate revocation or enrollment bar.

(13) **Affiliation that poses undue risk.** CMS determines that the provider or supplier has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

(14) **Other program termination or suspension.**

(i) The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other federal health care program, or the provider's or supplier's license is currently revoked or suspended in a State other than that in which the provider or supplier is enrolling. In determining whether a denial under
this paragraph (a)(14) is appropriate, CMS considers the following factors:

(A) The reason(s) for the termination, suspension or revocation.

(B) Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one State's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other State licensing boards or has had any other final adverse actions (as that term is defined in §424.502) imposed against it.

(C) Any other information that CMS deems relevant to its determination.

(ii) CMS may apply paragraph (a)(14)(i) of this section to the provider or supplier under any of its current or former names, numerical identifiers or business identities, and regardless of whether any appeals are pending.

(b) Resubmission after denial. A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred if the denial:

(1) Was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

(2) Was appealed, the provider or supplier may reapply after notification that the determination was upheld.

(c) Reversal of denial. If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

(d) Additional review. When a provider or supplier is denied enrollment in Medicare, CMS automatically reviews all other related Medicare enrollment files that the denied provider or supplier has an association with (for example, as an owner or managing employee) to determine if the denial warrants an adverse action of the associated Medicare provider or supplier.

(e) Effective date of denial. Denial becomes effective within 30 days of the initial denial notification.
Reapplication bar. CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 3 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.

(1) The reapplication bar applies to the prospective provider or supplier under any of its current, former, or future names, numerical identifiers or business entities.

(2) CMS determines the bar’s length by considering the following factors:

(i) The materiality of the information in question.

(ii) Whether there is evidence to suggest that the provider or supplier purposely furnished false or misleading information or deliberately withheld information.

(iii) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(iv) Any other information that CMS deems relevant to its determination.
APPENDIX C

42 C.F.R. § 424.535 sets forth the reasons that CMS may revoke a provider’s or supplier’s enrollment in the Medicare program. As revised, 42 C.F.R. § 424.535 Revocation of enrollment in the Medicare program states the following (the Final Rule’s revisions/additions are struck through and underlined, respectively):

(a) Reasons for revocation. CMS may revoke a currently enrolled provider or supplier’s Medicare billing privileges enrollment and any corresponding provider agreement or supplier agreement for the following reasons:

(1) Noncompliance. The provider or supplier is determined to not be in compliance with the enrollment requirements described in this subpart P or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

(i) CMS may request additional documentation from the provider or supplier to determine compliance if adverse information is received or otherwise found concerning the provider or supplier.

(ii) Requested additional documentation must be submitted within 60 calendar days of request.

(2) Provider or supplier conduct. The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is –

(i) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in §1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76.
(3) **Felonies.**

(i) The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses include, but are not limited in scope or severity to

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(iii) Revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(4) **False or misleading information.** The provider or supplier certified as “true” misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)
(5) **On-site review.** Upon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following:

(i) No longer operational to furnish Medicare-covered items or services.

(ii) Otherwise fails to satisfy any Medicare enrollment requirement.

(6) **Grounds related to provider and supplier screening requirements.**

(i)

(A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)

(A) Either of the following occurs: (1) CMS is not able to deposit the full application amount into a government-owned account. (2) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

(7) **Misuse of billing number.** The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in §424.80 or a change of ownership as outlined in §489.18 of this chapter.
(8) *Abuse of billing privileges.* Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

(A) Where the beneficiary is deceased.

(B) The directing physician or beneficiary is not in the state or country when services were furnished.

(C) When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) If CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:

(A) The percentage of submitted claims that were denied.

(B) The reason(s) for the claim denials.

(C) Whether the provider or supplier has any history of final adverse actions (as that term is defined under §424.502) and the nature of any such actions.

(D) The length of time over which the pattern has continued.

(E) How long the provider or supplier has been enrolled in Medicare.

(F) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination as to whether the provider or supplier has or has not engaged in the pattern or practice described in this paragraph.

(9) *Failure to report.* The provider or supplier did not comply with the reporting requirement specified in §§ 424.516 (d) (1) (ii) and (iii) of this subpart § 424.516 (d) or (e), § 410.33 (g) (2) of this chapter, or § 424.57 (c) (2). In determining whether a revocation under this paragraph (a) (9) is appropriate, CMS considers the following factors:
Whether the data in question was reported.

If the data was reported, how belatedly.

The materiality of the data in question.

Any other information that CMS deems relevant to its determination.

(10) **Failure to document or provide CMS access to documentation.**

The provider or supplier did not comply with the documentation or CMS access requirements specified in § 424.516 (f) of this subpart.

A provider or supplier that meets the revocation criteria specified in paragraph (a) (10) (i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

(11) **Initial reserve operating funds.** CMS or its designated Medicare contractor may revoke the Medicare billing privileges of an HHA and the corresponding provider agreement if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(12) **Medicaid Other program termination.**

Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

Medicare may not terminate unless and until a provider or supplier has exhausted all applicable appeal rights.

The provider or supplier is terminated, revoked or otherwise barred from participation in a State Medicaid program or any other federal health care program. In determining whether a revocation under this paragraph (a) (12) is appropriate, CMS considers the following factors:

(A) The reason(s) for the termination or revocation.

(B) Whether the provider or supplier is currently terminated, revoked or otherwise barred from more than one program (for example, more than one State's Medicaid program) or
has been subject to any other sanctions during its participation in other programs.

(C) Any other information that CMS deems relevant to its determination.

(i) Medicare may not revoke unless and until a provider or supplier has exhausted all applicable appeal rights.

(ii) CMS may apply paragraph (a) (12) (i) of this section to the provider or supplier under any of its current or former names, numerical identifiers or business identities.

(13) **Prescribing authority.**

(i) The physician or eligible professional’s Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional’s ability to prescribe drugs.

(14) **Improper prescribing practices.** CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.
(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s).

(E) Whether the physician or eligible professional has any history of “final adverse actions” (as that term is defined in §424.502).

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination.

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under section 1860D-2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

(15) Reserved.
Reserved.

Debt referred to the United States Department of Treasury. The provider or supplier has an existing debt that CMS appropriately refers to the United States Department of Treasury. In determining whether a revocation under this paragraph (a)(17) is appropriate, CMS considers the following factors:

(i) The reason(s) for the failure to fully repay the debt (to the extent this can be determined).

(ii) Whether the provider or supplier has attempted to repay the debt (to the extent this can be determined).

(iii) Whether the provider or supplier has responded to CMS' requests for payment (to the extent this can be determined).

(iv) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(v) The amount of the debt.

(vi) Any other evidence that CMS deems relevant to its determination.

Revoked under different name, numerical identifier or business entity. The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In determining whether a provider or supplier is a currently revoked provider or supplier under a different name, numerical identifier, or business identity, CMS investigates the degree of commonality by considering the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 application).

(ii) Geographic location.

(iii) Provider or supplier type.

(iv) Business structure.
(v) Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar.

(19) **Affiliation that poses an undue risk.** CMS determines that the provider or supplier has or has had an affiliation under §424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

(20) **Billing from non-compliant location.** CMS may revoke a provider's or supplier's Medicare enrollment or enrollments, even if all of the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. In determining whether and how many of the provider's or supplier's enrollments, involving the non-compliant location or other locations, should be revoked, CMS considers the following factors:

(i) The reason(s) for and the specific facts behind the location's non-compliance.

(ii) The number of additional locations involved.

(iii) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(iv) The degree of risk that the location's continuance poses to the Medicare Trust Funds.

(v) The length of time that the non-compliant location was non-compliant.

(vi) The amount that was billed for services performed at or items furnished from the non-compliant location.

(vii) Any other evidence that CMS deems relevant to its determination.

(21) **Abusive ordering, certifying, referring or prescribing of Part A or B services, items or drugs.** The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries,
or otherwise fails to meet Medicare requirements. In making its determination as to whether such a pattern or practice exists, CMS considers the following factors:

(i) Whether the physician’s or eligible professional’s diagnoses support the orders, certifications, referrals or prescriptions in question.

(ii) Whether there are instances where the necessary evaluation of the patient for whom the service, item or drug was ordered, certified, referred, or prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(iii) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s).

(iv) Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in §424.502).

(v) The length of time over which the pattern or practice has continued.

(vi) How long the physician or eligible professional has been enrolled in Medicare.

(vii) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(viii) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician's or eligible professional's ability to practice medicine, and the reason(s) for any such restriction, suspension, revocation, or termination.

(ix) Any other information that CMS deems relevant to its determination.
(b) **Effect of revocation on provider agreements.** When a provider’s or supplier’s billing privilege is revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

(c) **Reapplying after revocation.** If a provider, supplier, owner, or managing employee has their billing privileges revoked, After a provider or supplier has had their enrollment revoked, they are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar. The re-enrollment bar --

1. **The re-enrollment bar begins** 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 10 years (except for the situations described in paragraphs (c) (2) and (3) of this section), depending on the severity of the basis for revocation.

2. **The reenrollment bar does not apply** in an event a revocation of Medicare billing privileges is imposed under paragraph (a) (1) of this section based upon a provider or supplier’s failure to respond timely to a validation request or other request for information.

   (i) **CMS may add up to 3 more years** to the provider’s or supplier’s reenrollment bar (even if such period exceeds the 10-year period identified in paragraph (c) (1) of this section) if it determines that the provider or supplier is attempting to circumnavigate its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier or business identity.

   (ii) **A provider’s or supplier’s appeal rights regarding paragraph** (c) (2) (i) of this section --

      (A) Are governed by part 498 of this chapter; and

      (B) Do not extend to the imposition of the original reenrollment bar under paragraph (c) (1) of this section; and

      (C) Are limited to any additional years imposed under paragraph (c) (2) (i) of this section.

3. **CMS may impose a reenrollment bar of up to 20 years** on a provider or supplier if the provider or supplier is being revoked from Medicare for the second time. In determining the length of the
reenrollment bar under this paragraph (c) (3), CMS considers the following factors:

(i) The reasons for the revocations.
(ii) The length of time between the revocations.
(iii) Whether the provider or supplier has any history of final adverse actions (other than Medicare revocations) or Medicare or Medicaid payment suspensions.
(iv) Any other information CMS deems relevant to its determination.

(4) A reenrollment bar applies to a provider or supplier under any of its current, former or future names, numerical identifiers or business identities.

(d) Re-enrollment after revocation. If a provider or supplier seeks to re-establish enrollment in the Medicare program after notification that its billing privileges is revoked (either after the appeals process is exhausted or in place of the appeals process), the following conditions apply:

(1) The provider or supplier must re-enroll in the Medicare program through the completion and submission of a new applicable enrollment application and applicable documentation, as a new provider or supplier, for validation by CMS.

(2) Providers must be resurveyed and recertified by the State survey agency as a new provider and must establish a new provider agreement with CMS's Regional Office.

(e) Reversal of revocation. If the revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, or an authorized or delegated official; or a medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

(f) Additional review. When a provider or supplier is revoked from the Medicare program, CMS automatically reviews all other related Medicare enrollment files that the revoked provider or supplier has an association with (for example, as an owner or managing employee) to determine if the
revocation warrants an adverse action of the associated Medicare provider or supplier.

(g) **Effective date of revocation.** Revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(h) **Submission of claims for services furnished before revocation.**

(1) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(ii) A revoked HHA must submit all claims for items and services within 60 days after the later of the following:

(A) The effective date of the revocation.

(B) The date that the HHA’s last payable episode ends.

(2) Nothing in this paragraph (h) impacts the requirements of § 424.44 regarding the timely filing of claims.

(i) **Extension of revocation.**

(1) If a provider’s or supplier’s Medicare enrollment is revoked under paragraph (a) of this section, CMS may revoke any and all of the provider’s or supplier’s Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types.
(2) In determining whether to revoke a provider’s or supplier’s other enrollments under this paragraph (i), CMS considers the following factors:

(i) The reason for the revocation and the facts of the case.

(ii) Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments.

(iii) The number and type(s) of other enrollments.

(iv) Any other information that CMS deems relevant to its determination.

(j) Voluntary termination.

(1) CMS may revoke a provider’s or supplier’s Medicare enrollment if CMS determines that the provider or supplier voluntarily terminated its Medicare enrollment in order to avoid a revocation under paragraph (a) of this section that CMS would have imposed had the provider or supplier remained enrolled in Medicare. In making its determination, CMS considers the following factors:

(i) Whether there is evidence to suggest that the provider knew or should have known that it was or would be out of compliance with Medicare requirements.

(ii) Whether there is evidence to suggest that the provider knew or should have known that its Medicare enrollment would be revoked.

(iii) Whether there is evidence to suggest that the provider voluntarily terminated its Medicare enrollment in order to circumvent such revocation.

(iv) Any other evidence or information that CMS deems relevant to its determination.

(2) A revocation under paragraph (j)(1) of this section is effective the day before the Medicare contractor receives the provider's or supplier's Form CMS-855 voluntary termination application.
This article supplements two articles that previously appeared in *The Health Lawyer*:


The authors would like to thank Donald H. Romano, Esq. for his assistance with this article.


3 Comments to the Final Rule also were due November 4, 2019.

4 84 Fed. Reg. at 47794.

5 42 U.S.C. § 1395cc.


8 *Id.*

9 [https://www.ecfr.gov/cgi-bin/text-idx?SID=bf5ae9e9e53de3c3ba5485896892233ce51&mc=true&node=pt42.3.424&rgn=div5#sp42.3.424.p](https://www.ecfr.gov/cgi-bin/text-idx?SID=bf5ae9e9e53de3c3ba5485896892233ce51&mc=true&node=pt42.3.424&rgn=div5#sp42.3.424.p).

10 42 C.F.R. § 424.510.


12 The PECOS system is available here: [https://pecos.cms.hhs.gov/pecos/login.do#headingLv1](https://pecos.cms.hhs.gov/pecos/login.do#headingLv1).


15 Section 1902(kk)(3) of the Act requires states to require Medicaid providers and suppliers to comply with Section 1866(j)(5) of the Act.

16 Section 2107(e) of the Act makes Section 1902(kk)(3) of the Act applicable to CHIP.

16 See 42 C.F.R. § 424.519 (b), which requires the following:

Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms “owner” and “managing employee” as defined in § 424.502) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier that has a disclosable event (as defined in § 424.502). CMS will request such disclosures when it has determined the initially enrolling or revalidating provider or supplier may have at least one such affiliation.
84 Fed. Reg. at 47853. See also Appendix A, which sets forth the text of 42 C.F.R. § 424.519 as implemented.

Corresponding requirements related to disclosure to Medicaid are set forth at 42 C.F.R. § 455.107. Requirements related to disclosures to CHIP are set forth at 42 C.F.R. § 457.990.

17 Indirect partnership interests do not fall within the definition of partnership interests for the purposes of the regulation. 84 Fed. Reg. at 47799.


19 Id.

20 See Section 1124 (a) (3) of the Act.


22 Id. at 47802 and 42 C.F.R. § 424.519.

23 Id. and 84 Fed. Reg. at 47808.

24 Under the Final Rule, 42 C.F.R. § 424.519 (b) requires the following:

Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms “owner” and “managing employee” as defined in § 424.502) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid or CHIP provider or supplier that has a disclosable event (as defined in § 424.502). CMS will request such disclosures when it has determined the initially enrolling or revalidating provider or supplier may have at least one such affiliation.

See 84 Fed. Reg. at 47853.

25 After soliciting comments regarding whether there should be a monetary threshold for mandating reporting of uncollected debts, CMS declined to establish one. In particular, CMS stated, “Our preferred approach is to consider the debt’s amount as a factor in determining whether the debt presents an undue risk of fraud, waste, or abuse….In short, we believe that viewing the debt amount as one factor among several, rather than automatically excluding all smaller debts from consideration, will give us the necessary flexibility to address a variety of factual scenarios.” Id. at 47805. Declining to establish a monetary threshold for reporting uncollected debts leaves CMS discretion to deny or revoke a provider’s or supplier’s enrollment that has an affiliate with an uncollected Medicare debt that could be of de minimis value. Id.

26 Many commenters disagreed with including voluntary terminations within the scope of disclosable events. These commenters argued that including voluntary terminations was contrary to congressional intent, and further noted that many voluntary terminations are innocent and pose no program integrity risks. 84 Fed. Reg. at 47808. CMS disagreed with these commenters. In particular, CMS determined that including voluntary terminations within the scope of disclosable events is necessary to prevent situations where a provider or supplier voluntarily terminates his/her/its Medicare enrollment in order to avoid a revocation and reenrollment bar. Id.

27 Id. at 47800.

28 Id. at 47801.

29 Id. at 47802.

30 84 Fed. Reg. at 47811, citing 42 C.F.R. § 424.519 (e).

31 84 Fed. Reg. at 47810 and 42 C.F.R. §§ 424.519 (c) and (d).
See also 84 Fed. Reg. at 47817 and 42 C.F.R. § 455.107 (c) involving Medicaid claims. For purposes of disclosure to Medicaid, the Final Rule provides that, “affiliation disclosures are to be furnished ‘in a form and manner and at such time as determined by the Secretary.’ To comply with this requirement, we believe that states should consult with CMS as to the ‘form and manner’ of said disclosures.”

32 84 Fed. Reg. at 47811.

33 See Unlawful, Unfair and Unwise: Constitutional and Rulemaking Infirmities In CMS’s Enrollment Revocation Regulations and How to Challenge Them,” Donald H. Romano Esq., The Health Lawyer, Vol. 31, No. 6, August 2019 (taking the position that the lack of a right to respond pre-revocation is both illegal and unfair, and contrary to how the OIG runs its exclusion process).

34 84 Fed. Reg. at 47811.

35 Id.

36 Id.

37 In commentary to the Final Rule, CMS notes, “we understand the concerns about a provider’s or supplier’s ability to obtain debt (and other) data from affiliates.” Id. Although CMS may understand providers’ and suppliers’ concerns, the Final Rule does not provide leniency with respect to the disclosure requirements for events that a provider or supplier is unable to independently research.

38 Id. at 47812 and 42 C.F.R. § 424.519 (f).


40 Id. In response to a commenter’s expressed concern that “the lack of objective standards regarding undue risk creates a high potential for inconsistent determinations on comparable facts,” and suggestion that CMS adopt a decision matrix weighting relevant factors, CMS stated the following:

Response. We appreciate this suggestion but do not believe such a matrix is necessary or advisable. Given the vast variety of factual situations we will encounter, as stated previously, we must retain as much flexibility as possible in our undue risk determinations. We believe that elements such as “decision weights” would adversely impact our ability to fairly consider all of the facts, since it would effectively require that specific “scores” be given for certain criteria and circumstances.

41 Id. at 47814.

42 CMS will review PECOS data, other CMS databases and “external, non-CMS databases” to determine whether a provider or supplier has an affiliation with a provider or supplier with a disclosable event. Specifically, CMS will research whether an affiliate:

++ Currently has an uncollected debt to Medicare, Medicaid or CHIP.

++ Has been or is subject to a payment suspension under a federal healthcare program.

++ Has been or is excluded by the OIG for participation in Medicare, Medicaid or CHIP.

++ Has had its Medicare, Medicaid or CHIP enrollment denied, revoked or terminated.

43 Id. From the point of view of CMS, these events raise potential program integrity concerns of such significance to justify disclosure of all applicable affiliations. Id.
Id. and 42 C.F.R. § 424.519 (b). Despite the compliance phase-in, CMS retains the right to deny or revoke a provider’s or supplier’s Medicare enrollment based on that provider’s or supplier’s affiliation relationship before reporting is required under the regulations. See 42 C.F.R. § 424.519 (i).

44 84 Fed. Reg. at 47804.

45 Id. at 47794.

46 Id. at 47816 and 42 C.F.R. § 455.107 (b). However, CMS makes clear in its Final Rule that a state may deny or terminate a provider’s or supplier’s Medicaid or CHIP enrollment based on the provider’s or supplier’s affiliation relationships even before reporting is required under the regulations:

[Pl]er § 455.107 (h) and as addressed in more detail later in this section, if a state determines that a provider has an affiliation(s) – via a source(s) other than provider reporting – and determines, in consultation with CMS, that one or more affiliations of that provider represent an undue risk of fraud, waste, or abuse, the state may deny or terminate the provider’s enrollment in the state Medicaid program even before the state’s applications (or other means of capturing affiliation information, whether in physical or electronic form) have been updated with an affiliation disclosure section.

47 Id. at 47816.

48 Id.

49 Id.

50 Id.

51 Id.

52 Id. at 47801-47802.

53 Id. at 47804.

54 Id. at 47811.

55 Id. at 47814.

56 Appendix B includes the text of 42 C.F.R. § 424.530 prior to the implementation date of the Final Rule compared with the text of 42 C.F.R. § 424.530 as revised and supplemented by the Final Rule. Appendix C includes the text of 42 C.F.R. § 424.535 prior to the implementation date of the Final Rule compared with the text of 42 C.F.R. § 424.535 as revised and supplemented by the Final Rule.


59 Id.

60 Id.

61 Id. at 47823. “DMEPOS” refers to durable medical equipment, prosthetics, orthotics and supplies.

62 Id. and 42 C.F.R. § 424.535 (a) (20).

63 Id. at 47825.

64 Id.
A debt is legally enforceable only if there has been a final agency determination with respect to the obligation and there are no legal bars to collection action. The Medicare Financial Management Manual (CMS Internet-Only Publication 100-06), Chapter 4, Section 70.6, clarifies that overpayments “in appeal status (pending at any level)” constitute debts ineligible for referral. Therefore, if a provider or supplier receives an overpayment demand and submits an appeal of the initial determination, that “debt” is ineligible for referral until the appeals process has concluded.

Id. at 47828.

Id.


Id. at 47829.

Id.

Id.

Id.

Id. at 47830.

Id. at 47831. See also 42 C.F.R. § 405.371.

Id. at 47831.

Id. at 47854.

Id. at 47831.

Id.

Id.

Id. at 47832.

Id. at 47831.

Id. at 47832.

Id.

Id. at 47833.

Id.

Id.

Id. at 47826.

If CMS determines that it is appropriate to impose an additional three-year reenrollment bar under this section, a provider or supplier may appeal this determination. The appeal would be limited to the additional three-year period; it would not extend to the original reenrollment bar. Id.

Emphasis added.
92 Id. at 47827.
93 Id.
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The A, B, Cs (along with CDCs and FDAs) of Regulatory Implications over Assisted Reproductive Technology

By Kimberly J. Gold, Esq., Reed Smith LLP, New York, NY and Marla Neufeld, Esq., Greenspoon Marder LLP, Ft. Lauderdale, FL

 Brief History of Assisted Reproductive Technology

   In the United States, there is an ever-present and growing need for assisted reproduction, as nearly 10 percent of women (6.1 million) ages 15 to 44 have difficulty getting pregnant or staying pregnant.1 Yet, as science and medicine advance, assisted reproductive technology (ART) continues to change how people plan and grow their families.

   According to the American Bar Association’s Guide to Assisted Reproduction: Techniques, Legal Issues, and Pathways to Success (ABA Guide), ART, including in vitro fertilization (IVF), is considered one of the top medical advancements in the past 65 years, on par with the creation of antibiotics, forever changing the way people create families. It is now possible that a pregnant woman can carry and give birth to her child without having provided the genetics (egg donation); a couple can have a child who is carried by the mother but is genetically related to neither parent (embryo donation); a couple can have a child to whom they are both genetically related yet a third party gives birth to the child (gestational surrogacy),3 just to name a few of these possibilities.

   While attempts at IVF date back to the 1890s with the first reported case of an embryo transfer4 in rabbits, the birth (pun intended) of IVF occurred in 1978 in the United Kingdom, where Lesley Brown and her husband, John, had failed to conceive after attempting pregnancy for nine years. Without conducting any type of egg stimulation, Lesley underwent laparoscopic egg retrieval.5 British physiologist Robert Geoffrey Edwards took John’s sperm and fertilized the retrieved egg in the lab. A few days later, an eight-cell stage embryo was transferred inside Lesley’s uterine cavity. At 11:47 p.m. on July 25, 1978, 5 lb. 12 oz. Louise Brown, who was then called a “test tube baby,” was safely delivered by cesarean section. By the birth of Louise Brown, the world celebrated what was once an in-“conceivable” feat. A new era of assisted human reproductive technology has now contributed to more than five million babies conceived through IVF around the world.

 Typical Medical Procedures Involved in ART and Traditional vs. Gestational Surrogacy

   Common ART medical procedures aiding in pregnancy include (1) intrauterine insemination (IUI), a form of artificial insemination, in which the sperm is transferred via a medical device directly in a woman’s uterus around the time of ovulation, and (2) the most common form of ART, in vitro fertilization (IVF), in which the egg and sperm are fertilized outside the body in a laboratory and the resulting embryo(s) is/are transferred to a woman’s uterus.
Traditional surrogacy, which is often akin to a form of adoption as it allows the birth mother a period of time to change her mind and keep the child, means the surrogate uses her own egg in the conception of the child. Traditional surrogacy was most notably raised in the media in the early 1980s with the case *In the Matter of Baby M*. In *Baby M*, a traditional surrogate, Mary Beth Whitehead, fled New Jersey with the baby she was carrying for William and Elizabeth Stern and challenged the intended parents’ parental rights, wanting to keep the child. The child was conceived through insemination with the sperm of William Stern and the egg of Mary Beth Whitehead, the traditional surrogate. The New Jersey Superior Court initially ruled in favor of the Sterns; however, following lengthy litigation, the Supreme Court of New Jersey found the surrogacy contract to be unenforceable and ordered the Family Court to determine legal custody of the child. Ultimately the Sterns were awarded custody of the child with visitation rights granted to Mary Beth Whitehead.

In contrast to traditional surrogacy, gestational surrogacy means the surrogate has no genetic connection to the child. The arrival of IVF meant an embryo with absolutely no genetic connection to the surrogate could be transferred into the surrogate’s uterus, effectively eliminating, in many cases, the surrogate’s ability to retain parental rights to the resulting child. The genetics for the embryo transferred into a surrogate can be a variety of combinations, including the genetics of both members of the intended parents, the use of a donor egg, donor sperm, or donor embryo (with both the egg and sperm donated). The seminal case acknowledging gestational surrogacy was *Johnson v. Calvert* where the Court upheld surrogacy contracts as enforceable in the case of gestational surrogacy (the facts involved the parents’ egg/sperm transferred into a surrogate who had no genetic connection to the resulting child).

Within the case’s concurring opinion:

> Surrogacy contracts touch upon one of the most, if not the most, sensitive subjects of human endeavor. Not only does the birth of a new generation perpetuate our species, it allows every parent to contribute, both genetically and socially, to our collective understanding of what it means to be human. Every child also offers the opportunity of a unique lifetime relationship, potentially more satisfying and fulfilling than any other pursuit.

**Laws that Regulate ART**

ART is governed by state law, and the ART legal landscape in the United States varies across the country. The law is also rapidly changing. Each state has different laws regarding surrogacy and other ART forms like egg donation (i.e. California, Florida and Illinois have a legal framework for surrogacy, Georgia has no surrogacy statutes and is governed by case law and in New York it is a criminal offense to compensate a surrogate (with pending legislation to change)). Determining the applicable state law to apply to ART requires consultation with an ART legal practitioner to determine whether the process is permissible, considering that many times the intended parents may be located in one state (or country), the surrogate in another state.
and the fertility clinic in a different state, as well. State law also provides regulation over medical and legal licensing requirements, continuing medical and legal education, and discipline for medical and legal misconduct regarding ART professionals.

Constitutional principles also impact the ART legal landscape. Pursuant to the ABA Guide, the major right relates to the surrogate’s right to make decisions as they relate to her body — the constitutional right under the 14th Amendment of the Constitution and Supreme Court cases to bodily autonomy. Even if a gestational surrogacy contract provides that the surrogate will terminate the pregnancy if a doctor determines there is a genetic abnormality or other problem, the gestational surrogate has the right under the Constitution to change her mind based on the constitutional right to her body, and the only remedy the intended parents may have is to recover the money paid to the gestational surrogate and any third parties (which may be difficult to get back). The intended parents cannot force a gestational surrogate to terminate the pregnancy, and the intended parents will need to accept custody of the child regardless of any impairment.

Other constitutional principles that arise in the ART context include the right to procreate stemming from Supreme Court cases and the Full Faith and Credit Clause. In *V.L. v. E.L.*, a same-sex female couple sought for the non-biological mother to adopt their child in Georgia before the couple eventually separated while living in Alabama. The biological mother argued that Alabama should not recognize the Georgia adoption order. The case made it to the Supreme Court, which held that: “With respect to judgments, ‘the full faith and credit obligation is exacting…. A final judgment in one State, if rendered by a court with adjudicatory authority over the subject matter and persons governed by the judgment, qualifies for recognition throughout the land.’ A State may not disregard the judgment of a sister State because it disagrees with the reasoning underlying the judgment or deems it to be wrong on the merits.”

With many international intended parents coming to the United States to have children via surrogacy, international laws must also be considered to ensure that the intended parents will not have difficulties returning home with their child(ren) once born in the United States. U.S. laws and policies may also affect parents who are not American citizens. For example, under the Department of State (DOS) interpretation of policy Section 301 of the Immigration and Nationality Act, children born to same-sex couples are treated the same way as children born out of wedlock for purposes of determining United States citizenship. Despite the legalization of same sex marriage at the federal level, the DOS requires a biological father to show a blood relationship by clear and convincing evidence and meet a five-year residency requirement. This policy is currently being challenged. In *E.J. and A.J. Dvash-Banks v. Pompeo*, a unique outcome occurred where twin brothers were born via surrogacy in Canada and one child received a U.S. passport but the other was denied a U.S. passport due to the different genetics of the children and the citizenship of the parents. The parents are a same-sex male couple. One child was created by the sperm of a U.S. citizen, and one child was created by the sperm of the parent who was not a U.S. citizen. Despite the fact that the couple was married, they were treated as if
their children were born "out of wedlock" which triggered different residency requirements to issue a U.S. Passport. This decision was challenged in a California court, which ruled that both children acquired U.S. citizenship at birth and ordered DOS to issue the second brother a U.S. passport. The DOS appealed the ruling to the U.S. Court of Appeals for the Ninth Circuit to determine whether both children should be issued a U.S. passport.17

Other Regulations/Stakeholders in ART

The American Society for Reproductive Medicine (ASRM), an organization further described below, asserted that “[a]fter examination of the complex network of state and federal regulation as well as professional self-regulation governing ART practice, we conclude that Assisted Reproductive Technologies are among the most regulated medical procedures in the United States.”18

Federal agencies involved with the ART industry include, but are not limited to: (1) the Centers for Disease Control and Prevention (CDC), which collects ART cycle data, publishes an annual report and develops a model program for the certification of IVF laboratories; (2) the Food and Drug Administration (FDA), providing regulation of drugs, biological products, and medical devices, screening and testing of donor tissues (since ART involves handling of human tissue), and requiring mandatory registration of all ART medical programs with the federal government; (3) the Clinical Laboratory Improvement Act (CLIA), implemented by the Centers for Medicare & Medicaid Services (CMS) which ensures quality over IVF clinic laboratories via laboratory inspections and accreditation; and (4) the American Association of Tissue Banks (AATB), which provides screening guidelines for donors of embryos and genetic material.

Some important partners who represent consumers of ART and provide infertility services such as advocacy, funding and education include RESOLVE, Path 2 Parenthood, and Livestrong Fertility. These organizations work in partnership with the CDC.

The ART industry also has self-regulatory organizations which establish guidelines, recommend best practices, provide educational opportunities, and issue ethical opinions for professionals in the ART community as seen in organizations such as ASRM and the ASRM affiliate, Society for Assisted Reproductive Technology (SART).

Recent Expansion of ART

Typically, the more standard treatments and procedures aimed at achieving pregnancy, such as IVF or surrogacy, are what come to mind when thinking about ART. However, the scope of ART has become much broader. Since its inception, ART has grown into a multi-billion-dollar market, and the field is only continuing to expand with emerging scientific and technological advancements.
In 2016, the global ART market was valued at $21.9 billion, and is projected to reach over $36.7 billion by 2025. In the past three years alone, an estimated $1 billion has been poured into women’s health technology, known as “femtech” – which is one of the largest and most accessible forms of ART. Femtech includes period and fertility tracking apps, such as Clue and Glow, the Fitbit app’s “female health tracking” feature, which tracks period and ovulation data, as well as NextGen Jane’s “smart tampon,” which is used to detect early signs of disease that may affect women’s fertility and overall reproductive health.

Beyond the femtech sphere, scientific advances have greatly expanded the possibilities of ART. For example, advances made with CRISPR-Cas9, popularly referred to as “CRISPR,” create the potential to use genetic engineering to modify the genetic makeup of an embryo and create so-called “designer babies.” Commercial DNA tests can be used to track sperm donors and confirm paternity. Posthumous reproduction can be used to create life after death by using frozen sperm, eggs or embryos, and uterine transplants can be used to treat infertility by replacing an absent or diseased uterus with a healthy one. In addition, companies such as CiceroDx and Juneau Biosciences have created advanced non-invasive diagnostic testing for endometriosis, a common cause of infertility. The capabilities of ART will only continue to grow.

Issues with Period and Fertility Tracking Apps

The most widespread and accessible form of femtech ART is period and fertility tracking apps. In a 2018 study of 1,000 women, approximately one quarter (23.1 percent) reported currently using or had used in the recent past a fertility app, and 76.9 percent reported their intention to use one in the future. In fact, period and fertility tracking apps are the fourth most popular type of mobile app among adults, and second most popular among adolescent women. These apps are incredibly useful for users as they capture information regarding, among other things, women’s menstrual cycle, sexual activity, pregnancy status and miscarriages in order to give users more insight into their fertility. Some apps even allow women to share personal stories about their fertility journeys on forums within the app. By allowing users to closely monitor their reproductive health in a way that was never possible before, these fertility and period tracking apps allow for more effective and efficient family planning.

Beyond the benefits to the user, the data collected by tracking apps offer great opportunities to advance ART and reproductive health. The data collected through these apps provide companies with the potential to derive financial value from the data and present new treatment options.

However, the accuracy of these apps has been questioned, considering very few of them undergo scientific testing to ensure their accuracy. There are approximately 100 period and fertility tracking apps that currently exist on the market. A recent study found that only 30 of these apps purport to predict fertile days for a user, and only six of those 30 apps were found to
accurately identify the fertile window.\textsuperscript{26} One of these apps, the Swedish-made contraceptive device Natural Cycles, recently came under criticism after several users became pregnant while using it.\textsuperscript{27} While Natural Cycles was under investigation for these pregnancy reports, the FDA authorized the marketing of Natural Cycles, making it the first, and as of now, only, app of its kind to be approved by the FDA.\textsuperscript{28}

In addition to accuracy concerns, there are other barriers that currently stand in the way of these apps achieving their full potential. First, evidence shows that many of these apps are still designed and produced by men, and as a result, these apps often do not acknowledge or even completely misinterpret the full range of women’s needs, sometimes having serious repercussions.\textsuperscript{29} Second, the tracking apps and other femtech have historically struggled to receive venture capital funding. The lack of funding may be attributed to the abundance of male investors (which account for approximately 94 percent of the decision makers in the U.S. venture capital market), who may struggle to understand the health needs of women and the value proposition of women-oriented products.\textsuperscript{30} Third, less research has been done to understand the use of fertility apps as a form of contraception, and their efficacy in such prevention. In hopes to provide clarity on the matter, the FDA released a Digital Health Innovation Action Plan,\textsuperscript{31} which looks at ways in which the agency regulates digital health technologies such as the FDA-approved Natural Cycles app.\textsuperscript{32} Fourth, as further discussed below, privacy concerns are prevalent, considering the wide scope of data sharing that occurs through these apps.

**Rising Privacy and Cybersecurity Implications with Emerging Femtech ART**

Using fertility apps and other forms of femtech ART require the user to share a tremendous amount of information, much of it sensitive and private. And with such data, there is a growing concern as to how individuals’ privacy is being protected. While an immense amount of individually identifiable health information is shared with emerging femtech ART, there are currently minimal regulations and protections with respect to such data sharing. There is a common misconception that ART applications and other femtech are regulated by the Health Insurance Portability and Accountability Act of 1996\textsuperscript{33} (HIPAA) regulations, because they encompass health data, but this is often not the case. What HIPAA does cover are “covered entities,” which include health plans, health care clearinghouses, health care providers that perform certain types of electronic transactions, and their vendors or “business associates.” However, many ART research organizations and clinics, as well as femtech and mobile app developers working on ART solutions, are not directly subject to HIPAA’s privacy and security standards. Instead, they are often left to implement security measures and safeguards in line with industry standards or as they deem reasonable, leading to inconsistencies and vulnerabilities in the protection of personal data. For example, in 2016 Consumer Reports tested Glow, a mobile app designed to help women track their period and fertility, for security and privacy features. What Consumer Reports found was alarming – one security flaw would have allowed a person with no hacking skills to access a women’s personal data, while other flaws would have allowed
a hacker to collect email addresses, change passwords, and access personal information from participants in community forums.³⁴ Glow quickly updated the app to patch the security issues and notified customers of the issue, and indicated that no customer data had been compromised.³⁵

Another example of a security vulnerability is the lack of transparency with respect to data sharing with third parties. In 2019, the Wall Street Journal found that a number of popular healthcare apps share personal and health data with Facebook.³⁶ In particular, it found that the Flo Period & Ovulation Tracker shared with Facebook information on when a user was having her period. In addition, UK-based advocacy group Privacy International discovered that tracker apps, including MIA Fem and Maya, were sending personal information about women’s health and sexual practices directly to Facebook.³⁷ Privacy International concluded that out of the 36 apps it tested, 61 percent automatically transfer data to Facebook the moment a user opens the app, regardless of whether the user was logged into Facebook or had an account.³⁸ So, while data from tracking apps and other femtech can provide companies with financial value, companies will also need to consider the marketing and overall transparency requirements under the FDA and the Federal Trade Commission (FTC).³⁹

There are also other laws and regulations that may apply to ART, which may ultimately cause potential confusion for ART providers and consumers and inconsistency within the field. Many states are implementing new privacy laws that go beyond the scope of HIPAA, such as the California Consumer Privacy Act (CCPA), which has a particularly broad definition of what constitutes “personal” data, and has heightened security and privacy requirements.⁴⁰ For example, the CCPA and HIPAA articulate different standards for de-identified data.⁴¹ In addition, several states have either enacted legislation or have pending privacy bills, which contain varying obligations with respect to prior consent when collecting or sharing consumer data.⁴² Therefore, with the increasing prevalence and severity of data breaches, and with new privacy laws going into effect that require reasonable security measures and greater consumer data rights, ART providers, researchers, and apps will need to address the privacy and security implications of collecting and storing consumer data.

Conclusion

ART is a dynamic and rapidly evolving field, with new technologies continually creating new capabilities and opportunities. While giving hope to millions of couples experiencing infertility, ART has also introduced new social and legal questions. As a result, the regulatory implications continue to evolve to accommodate and respond to these unique questions created by ART.

This article is based on a presentation given by Kimberly Gold, Marla Neufeld and Dr. Sharon Jaffe at the 20th Annual Conference on Emerging Issues in Healthcare Law, “Third Party
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2 “Assisted Reproductive Technology” means procreative procedures which involve the laboratory handling of human eggs, sperm or embryos.

3 “Third Party ART” means human reproduction in which genetic material or gestation is provided by a third party, other than the person/people intending to raise the child (i.e. egg donation or surrogacy).

4 “Embryo transfer” means the medical procedure of transferring embryos into intended mother/surrogate.

5 “Retrieval” means the medical procedure of surgically removing eggs from an egg donor.


7 “Intended parents,” or a “commissioning couple,” means the parent(s) intending to have a child(ren) conceived by means of ART.

9 Johnson v. Calvert, 5 Cal.4th at 101-201.

10 California Code, Family Code - FAM § 7962.

11 Florida Statutes 742.15.

12 (750 ILCS 47/) Gestational Surrogacy Act.


15 Id. at 1020.


17 Dvash-Banks v. U.S. Dep’t of State, No. 19-55517, 2019 WL 5296486 (9th Cir. October 11, 2019).


21 https://www.biospace.com/article/new-test-brings-hope-and-new-answers-for-unexplained-infertility-failed-ivf-and-miscarriage/?utm_campaign=GenePool&utm_source=hs_email&utm_medium=email&utm_content=76996169&_hsenc=p2ANqtz-9AgBOzCk6c0M74aKdH_NF8qlxRCZACoD8xalyT_kTivexNy2mVCXKLSrRH0obCy6GgCHlf9YnhyRLG5bM0OyLBrTg&_hsmi=76996169.

22 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6043758/.


The Natural Cycles app was cleared by the FDA under a process specifically designed for new types of medical devices called De Novo classification. Along with this authorization, the FDA is establishing criteria, called special controls, in hopes to clarify the agency’s expectations in assuring the accuracy, reliability and effectiveness of these apps as a form of contraception. https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy.


https://www.lexology.com/blog/2019/05/the-future-is-femtech.

In September 2019, the FDA provided new guidance to continue the efforts outlined in the Digital Health Innovation Action Plan and to offer additional clarity about where the FDA sees its role in advancing safe and effective digital health technologies. Initial guidance topics include clinical decision support software and changes in medical software policies resulting from Section 3060 of the 21st Century Cures Act. https://www.fda.gov/news-events/press-announcements/statement-new-steps-advance-digital-health-policies-encourage-innovation-and-enable-efficient-and.


40 AB375, Title 1.81.5, The California Consumer Privacy Act of 2018. The CCPA is designed to protect the privacy and data of consumers. The Act requires businesses to tell consumers what data it is collecting and gives consumers the right to say no to the sale of their personal information. It will also allow consumers to sue companies in the event their personal data is breached.

For example, California, Maine, Nevada, and Texas enacted privacy legislation with varying consent and notice requirements, while nearly 10 other states have privacy bills pending in committees. https://iapp.org/news/a/us-state-comprehensive-privacy-law-comparison/.
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Re-Assessing Antitrust Policies and Actions Regarding Independent Physicians to Preserve Healthcare Competition: It’s Time to Revise the Rule of Reason Analysis

By Michael T. Goldstein, M.D., J.D., New York, NY

Introduction

The Federal Trade Commission (FTC) and the Department of Justice (DOJ) are charged with the enforcement of the antitrust laws. According to the FTC’s website, “[c]ompetition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. The Federal Trade Commission's job as a law enforcer is to stop firms from engaging in anticompetitive conduct that harms consumers.” FTC and/or DOJ prosecutions in anticompetitive situations are effective and upheld by district and appellate courts. They also enable the agencies to protect the public.

Unfortunately, that is only part of the picture. Healthcare consolidation is a complex multifactorial issue; despite these enforcement actions, healthcare entities are combining, and competition is decreasing. Hospitals are vertically integrating by acquiring physician practices and horizontally integrating by merging. Insurance companies have merged to the point that there now are only a handful of major ones. Vertical integrations among insurance companies, pharmacy benefit managers and other entities are ongoing. Cost-effective smaller independent physician and other provider practices are disappearing, mostly by acquisition. The result is a less competitive marketplace.

The disappearance of the independent physician is due to a number of factors, including increasingly complex regulatory compliance burdens, cumbersome and time-consuming value-based reporting requirements, and the huge educational debt incurred by recent medical school graduates, which make it more difficult for a physician to be or remain independent. An additional factor is physicians’ inability to form collaborative joint ventures within the antitrust laws that would enable them to bargain collectively while still maintaining their independence. A review of recent enforcement actions against independent physicians’ joint ventures reveals several different models that have failed to pass antitrust scrutiny. The structure of the collaboration determines the applicable standard the FTC uses to analyze the case. Those that attempt to engage in price fixing are classified as “violations per se” and are appropriately prosecuted. However, physician joint ventures that attempt to do more than just raise prices are analyzed under either “inherently suspect analysis” or “rule of reason analysis” which uses a three-part test. Rule of reason analysis is an evolving process, and ultimately is about comparing the pros and cons of what would have otherwise been an anticompetitive joint venture.

Because of the decline of independent physicians, healthcare consolidation and reduced competition, it is time for the rule of reason analysis to be revised when evaluating independent physician joint ventures. This change will aid in achieving the FTC’s goal of preserving competition.

This article will review the categories of antitrust actions against independent physicians joining together for bargaining and other purposes, and offer suggestions as to how the rule of reason
analysis should be modified and adapted to physician joint venture models to help preserve competition.

**The Independent Practice Paradox**

The percentage of independent physicians in the United States has decreased from 57 percent in 2000 to 33 percent in 2016. This changing practice demographic is relevant because the preservation of this group is essential to the goals of the antitrust laws to preserve competition as a means of controlling costs. According to a 2010 study conducted by the attorney general of the state of Massachusetts, there is a 300 percent difference in healthcare costs between the lowest and highest paid providers not because of a difference in quality but due to bargaining power. The study also found that it was bargaining power and not the payment system used that affected the cost of healthcare. A Commonwealth Fund report found that both horizontal mergers between hospitals and vertical integration between hospitals and physician groups raise costs without improving quality. Another study found an 8-26 percent higher price for 12 common procedures in markets with the highest concentrations of physician groups. Consolidation not only raises prices without improving quality, but in some instances can result in increased costs associated with unnecessary hospitalization. According to a more recent study, “practices with one to two physicians had 33 percent fewer preventable hospital admissions than practices with 10 to 19 physicians and practices with three to nine physicians had 27 percent fewer admissions.”

In traditional goods-driven markets, large sellers such as supermarkets, big box hardware stores and online retailers use their huge market clout to pay less for goods and then sell them to consumers at a lower price. In contrast, typically in healthcare the transaction is between the payor, usually an insurance company or the government, and the seller of care, an integrated healthcare system, medical group or small providers on behalf of the consumer of that care. The larger healthcare sellers have more bargaining power and can sell their services at a higher price.

Another advantage of the large sellers is that they can add ancillary healthcare services to their income stream. For example, when St. Luke’s Health System acquired Saltzer Medical Group, the largest independent specialty physician practice group in the Nampa, Idaho area, it not only enabled St. Luke’s to dominate the primary care physician market, it also enabled St. Luke’s to shift the Medical Group’s laboratory business from the Group to itself at a higher cost to payors. When in addition to the higher procedure costs and higher associated costs (i.e., lab costs and facility fees that would not be available to small practices) the cost differential between the independent practitioners and the integrated entities widens. This additional downstream revenue incentivizes hospitals to acquire physician practices, reducing competition further.

The above suggests that independent practices are cost-effective competitors of larger integrated entities, and from an antitrust perspective preserve competition and help control costs. For the above reasons the antitrust regulatory process should function in a manner to halt and hopefully reverse the shifting of physicians from independent practice to larger entities like vertically integrated hospital systems and large group practices.
Relevant Antitrust Laws

There are three antitrust laws that govern the actions of the FTC and the DOJ with regard to healthcare. The agencies share jurisdiction in this area. The FTC has focused on hospital and practice mergers and physician joint ventures, while the DOJ has focused on insurance company mergers. In cases where the FTC finds criminal activity the two agencies collaborate.

Sherman Antitrust Act, 15 U.S.C. §§ 1-2. The nature of the violation of this multipronged statute is usually applied in FTC cases relating to conspiring or engaging in price fixing and/or joint boycotts.12

Section 7 of the Clayton Act, 15 U.S.C. § 18.13 The Clayton Act prohibits acquisitions that have the effect of substantially lessening competition or tend to create a monopoly.14

Section 5 of the FTC Act, 15 U.S.C. § 45.15 This provision empowers the FTC to investigate and prosecute entities engaged in unfair methods of competition.

State Jurisdiction in Antitrust Regulation: The State Action Doctrine. The jurisdiction of the FTC over an alleged antitrust violation has limitations. Under the State Action Doctrine, state economic regulation can immunize private parties from federal antitrust liability if a state substitutes its control of the market instead of allowing federal control.16 For this doctrine to apply to private parties, the state “must demonstrate that the challenged conduct was both (1) undertaken pursuant to a clearly articulated state policy to displace competition with regulation and (2) actively supervised by state officials.”17

Methodology of Review

The FTC views independent physician joint ventures based on their structure. Independent physicians forming joint ventures purely to collectively negotiate higher fees are analyzed using the price fixing clause of the Sherman Antitrust Act and/or Section 5 of the FTC Act, which protects against unfair methods of competition.

When the FTC analyzes a case, the intensity of the process is dependent on the nature of the alleged violation. Cases which are classified as ”violations per se” are not subject to any additional analysis. Joint ventures that involve something more than just price fixing but similar to previous successful prosecutions are subject to “inherently suspect analysis,” which is an abbreviated review process.

As noted above, when the joint venture involves other aspects, including potentially procompetitive offsets, it is subject to the rule of reason analysis. Rule of reason analysis is a three-part test, which involves determining the relevant market, the anticompetitive effect, and a procompetitive efficiency defense.18 The burden of proof for the first two parts falls on the government, and the burden of proof for the third part shifts to the defendant.

According to the FTC, two examples of procompetitive efficiency enhancing actions under the rule of reason are (1) risk sharing contracts19 and (2) clinical integration designed to increase efficiency and that creates “interdependence and cooperation among physicians to control costs and ensure quality.”20
Representative Enforcement Actions

Cases run the gamut of naked price fixing, where competitors meet and agree to raise prices, to messenger model IPAs attempting to collectively negotiate, to more but not sufficiently integrated joint ventures, or pseudo joint ventures engaged in collective negotiation.

Violations Per Se

In *US v. Alston* there was nothing more than competitors with no organizational structure attempting as a group to raise prices. Dentists who were providers in a prepaid dental plan in Tucson, Arizona were paid by capitation and copayment fees. Some of the dentists had individually approached a health plan requesting higher fees without success. Some fees, such as for porcelain crowns, were so low that the dentists were not even breaking even on the service. Three dentists, Drs. Alston, Meyer and Walker, organized a meeting of approximately 50 dentists in Dr. Alston’s office to discuss the problem, resulting in many of the dentists sending a form letter to the insurance company requesting higher fees. This resulted in an increase of some of the fees. The DOJ obtained a criminal indictment against Alston, Meyer and Walker for “conspiring to fix prices in violation of section 1 of the Sherman Act.”

There are also a large number of violation per se cases involving messenger model independent practice associations (IPAs) where the IPA engaged in collective negotiations. These include *Southwest Health Alliance*, *Roaring Fork Valley Physicians IPA, Inc.*, *Boulder Valley Individual Practice Association*, and *Independent Physician Associates Medical Group, Inc.* In all of these cases, the IPA negotiated collectively for the independent physicians, would not permit them to negotiate individually with the insurance companies, and set the price that all of its members would accept. There was no clinical integration nor any efficiency defenses that would warrant rule of reason analysis. These were all prosecuted under 15 U.S.C. § 45 for price fixing or joint boycotting. They could have also been prosecuted under the Sherman Act, which the courts have deemed equivalent to 15 U.S.C. § 45.

For example, in *Roaring Fork Valley Physicians IPA, Inc.* a messenger model IPA of approximately 85 independent, competing physicians and physician groups in the Garfield County, Colorado area (1) refused to deal with payors except on collectively agreed upon terms; (2) coordinated agreements of its members on price related terms; and (3) as a condition of joining the IPA required its member physicians to sign an agreement that they would refuse to enter into contracts except on Roaring Fork’s collectively agreed upon terms.

Inherently Suspect Analysis

Cases that fit this category of review are ones where the case so closely resembles previous ones that the FTC uses an abbreviated review process. In this process, the cases are expedited, and decisions are made in accordance with those of the previous cases rather than subjected to a full rule of reason analysis.

For example, in *In the Matter of North Texas Specialty Physicians* (NTSP) the IPA served a dual purpose: it negotiated capitation contracts, which was not part of the antitrust action, and it functioned as a messenger model IPA. The organization, formed in 1995, was originally
designed to negotiate capitated contracts with payors. It expanded into fee-for-service contracts as a messenger model IPA. It would annually survey its members, conduct a statistical analysis of the results, and improperly share the results with the members. Using that information, the IPA would negotiate contracts with payors as a messenger where each practice would individually accept or reject the contract. Despite the IPA’s obligation to forward all offers to its members, it would only forward the offer if the fee was high enough that 50 percent of the members would accept the contract.

The FTC charged NTSP of horizontal price fixing in violation of Section 5 of the FTC Act. The price fixing involved negotiating fee-for-service contracts not as a messenger model but instead actually negotiating collectively, in clear violation of the FTC Act. The FTC determined that there was no procompetitive component that justified the collective bargaining.

Since the conduct was obviously in violation, the FTC used the abbreviated inherently suspect analysis. Because NTSP was closer to meeting FTC collaborative joint venture requirements than Alston, it was subject to a more extensive review process than a per se violation.

In making its determination that NTSP was in violation, the FTC analyzed the procompetitive arguments made by NTSP and compared the fact pattern with that of numerous prior similar cases. Its decision was upheld by the appellate court.

**Rule of Reason Analysis**

The rule of reason analysis is used where antitrust issues are balanced against procompetitive benefits of the joint venture.

The first part of the analysis involves determining what the relevant market is. The second part determines if the joint venture, based on its market share in the relevant market, has the ability to raise prices above competitive levels. The third part is to determine if the procompetitive advantages of the joint venture outweigh the antitrust concerns. How one balances these factors determines the outcome.

Since any case of collaborative joint venturing has the potential to raise prices and reduce competition, it is usually the procompetitive advantages of the particular joint venture that determines whether it is deemed to be permitted under the antitrust laws. The standard that is used to determine what is procompetitive is outcome determinative in most cases. What that standard is and how it is in alignment with the market realities has a major impact on the effect of FTC enforcement actions regarding competition in marketplace.

The current standard articulated by the FTC to be procompetitive using rule of reason analysis is “[p]rice agreements among competing sellers, as a general rule, are price fixing and summarily condemned by antitrust laws as per se illegal. But joint price setting by provider networks is not per se illegal if: (1) the participants have integrated their activities through the network (whether financially, clinically or otherwise) in a way that is likely to produce significant efficiencies that benefit consumers: and (2) the price agreements are reasonably necessary to realize those efficiencies.”
For example, in *Minnesota Rural Health Cooperative* (MRHC) the entity was a collaborative joint venture consisting of 22 hospital members, 114 physician members practicing in 47 clinics and about 70 pharmacy members.\(^4^4\) Provider members of MRHC “agree that MRHC will negotiate and contract with health plans on their behalf and agree to participate in all MRHC contracts.”\(^4^5\) When payors contacted individual MRHC hospitals and physicians, they were referred back to MHRC.\(^4^6\)

In 2003 MRHC notified payor HealthPartners that it would not renew its payor contract unless there was a higher reimbursement rate.\(^4^7\) This resulted in a 27 percent higher reimbursement rate for MRHC physicians than comparable non-MRHC physicians.\(^4^8\)

MRHC was charged with violating Section 5 of the FTC Act “by among other things, orchestrating and implementing agreements among competing MRHC members to fix the price at which they contract with health plans and to refuse to deal except on collectively-determined price terms.”\(^4^9\) The FTC found that MRHC existed primarily for the purpose of bargaining and thus was in violation of Section 5 of the FTC Act.\(^5^0\)

Although there were procompetitive activities, including risk contracts with 10 percent withholding, a quality improvement project with reporting of compliance with clinical practice guidelines limited to a few medical conditions, such as diabetes, credentialing, monitoring of patient complaints, organizational meetings, and patient satisfaction surveys, the FTC did not believe that these activities, which were limited to the physicians, met the integration requirements under the procompetitive third part of the rule of reason analysis to justify collective negotiations.\(^5^1\)

The FTC noted that had MRHC actively integrated clinically or financially in a way that would have benefited consumers through cost saving procompetitive activity, it might have met the standards articulated by the FTC to bargain collectively for its members.\(^5^2\)

**Problematic Outcome: Payor Monopsony Still Results in Physician Antitrust Violation**

A recent example of how the rule of reason analysis may need updating in today’s healthcare environment involved physicians in Puerto Rico. Cooperativa de Medicos Oftalmologicos de Puerto Rico, a nonprofit organization representing over 50 percent of the ophthalmologists in Puerto Rico, refused to accept a Medicare Advantage plan contract from payor MCS Advantage that would reduce the physicians’ fees by 10 percent.\(^5^3\) The board of the Cooperativa met and notified its members not to accept the contract; the doctors, using the vehicle of the Cooperativa, jointly boycotted the plan and refused to take the lower fees.\(^5^4\) The doctors also refused to bargain individually with the payor.\(^5^5\) MCS Advantage filed an antitrust complaint against the Cooperativa.

According to the FTC’s 2017 consent order, the conduct of the Cooperativa was in violation of Section 5 of the FTC Act, which prohibits unfair methods of competition.\(^5^6\) The actions also violated the Sherman Act’s prohibition against joint boycotts.

However, the case points to one of the problems associated with enforcement without looking at the broader effects of the action on the marketplace.
Almost all antitrust cases involve issues in which an entity with unfair bargaining power attempts to raise prices above competitive levels. In contrast, *Cooperativa* involved an improperly structured joint venture resisting a monopsony attempting to lower prices.

A recent Commonwealth Fund study on the effects of consolidation evaluated the pros and cons of consolidation. The study found that one of the problems with consolidation is that it creates monopsonies in which a large buyer, i.e. an insurance company, drives the price down, which can result in low prices that reduce the “quantity or quality of services below the level that is socially optimal.” Moreover, price reductions are not necessarily passed onto to the consumer in lower costs.

The situation in Puerto Rico exemplifies the problem with the current enforcement regulations. The current market penetration in Puerto Rico of Medicare Advantage plans is more than 70 percent of the Medicare market. Reimbursement rates under these plans in Puerto Rico are 43 percent lower than the average reimbursement rate for such plans in United States overall and 26 percent lower than in the U.S. Virgin Islands. Many of the Medicare Advantage enrollees are insured by government assisted healthcare plans and are directed into these plans. Because of the current structure of the Puerto Rican healthcare system, between 2012 and 2017 reimbursement rates have dropped five to six percent per year.

According to Roberto Pando Cintron, the president of MCS Advantage, there has been a “mass exodus” of healthcare professionals from Puerto Rico. In addition, the combination of low reimbursement, scaring off of specialists and underpayment of the hospitals and healthcare systems has resulted in an underfunding of the healthcare infrastructure. This is all contributing to a decline in both the quantity and quality of healthcare services in Puerto Rico.

Moreover, physician shortages due at least in part to low reimbursement is not unique to Puerto Rico. For example, Nevada ranks number 48 out of 50 with regard to physicians per capita in part due to low reimbursement. These physician shortages are creating a crisis in healthcare delivery. Healthcare markets do not behave as traditional markets, and in areas of physician shortages reimbursement does not go up in order to attract physicians to underserved areas. Apparently in these markets, as in Puerto Rico, it is the payors that are keeping prices below competitive levels. To restore competitive balance in these markets, rule of reason analysis of physician joint ventures should factor in the societal procompetitive advantage that a collective bargaining entity plays in preventing or resolving a healthcare shortage.

### Current Rule of Reason Analysis Outdated

In this new world where driving prices down lowers quality, decreases access and reduces the ability of underpaid providers to upgrade and invest in new technology, the analysis of the behavior of a physician joint venture is more complex than in the past. The rule of reason analysis process should be updated to reflect the new realities.

Physicians have tried various strategies to achieve their goal of collective negotiation. Unfortunately, the models as applied have achieved limited success and have failed to halt the trend towards increased healthcare consolidation.
An example of a successful clinically integrated IPA that was designed to be compliant with the current antitrust regulations is Mount Sinai Health Partners (MSHP), located in New York. This is a recently formed and still evolving clinically integrated IPA consisting of several thousand employed and independent physicians and the Mount Sinai Healthcare System.\(^6\) This entity began with the Continuum Healthcare System prior to its acquisition by Mount Sinai and then was continued by Mount Sinai. It has taken many years and huge costs to reach the point where it became operational.\(^6\) However, forming a similar collaborative joint venture in compliance with the current regulations is beyond the ability of independent physicians without the help of an institutional partner. This is unfortunate, because the FTC’s goal of preserving competition with respect to the physician provider sector is not succeeding.

One solution may lie in regulatory reform. The standards under the third part of the rule of reason analysis should be adjusted to take into account the diminishing role that independent practices play in the healthcare marketplace and their need to collaborate with each other and with non-physician providers to form pro-competitive joint ventures.

Independent practices are cost-effective competitors, and from an antitrust perspective preserve competition and help control costs. The antitrust regulatory process should function in a manner to halt and hopefully reverse the consolidation that is shifting physicians from independent practice. For this to occur, the FTC should consider modifying its standard for evaluating the procompetitive advantages of collaborative joint ventures by independent physicians in the rule of reason analysis.

In the current model, the FTC looks at a particular joint venture of independent physicians and determines if there is price fixing by competitors, and then based on the integration and the procompetitive advantages under the rule of reason analysis determines if the joint venture is in compliance or in violation of the antitrust laws. The rule of reason analysis applies to the specific entity.

A potential way to preserve competition and control costs is to modify the third part of the rule of reason analysis to analyze the procompetitive advantages of the joint venture not as it specifically applies to the joint venture but instead as to how it affects the broader market. For example, if a physician joint venture fell short of meeting the current procompetitive requirements under the rule of reason analysis, there should be a second component to the third step of the analysis that would assess the procompetitive role of the joint venture in preserving competition in the broader market. If the entity had a net positive effect of preserving competition and controlling costs in the overall market, even if it raised prices for the joint venture, and the prices were still below those of the consolidated entities that dominate the market, then the venture should be permitted. This analysis should be flexible enough to preserve competition in troubled markets, such as Puerto Rico. This modification of the rule of reason analysis could be accomplished by administrative adjudicative rulemaking based on case law or rule revision subject to notice and comment.

Another potential revision to the rule of reason analysis is to provide for greater flexibility in the second part of the rule of reason analysis, which analyzes the joint venture’s ability to raise
prices above competitive levels using the HHI index.70 The lower this index, the less likely a joint venture will have the ability to raise prices in the market. This can then be applied to the analysis of whether the joint venture has pro or anticompetitive effects. Greater flexibility under the rule of reason analysis should be given to entities with low HHI indexes because of their lower impact on the overall market.

In addition, the rule of reason analysis should be adaptable and permit innovative new models of collaborative joint ventures to enter the market, such as physician guilds affiliated with medical societies, physician cooperatives, and other innovative forms of physician joint venturing, provided that these entities achieve procompetitive goals. Messenger model IPAs in very consolidated markets might on a case by case basis be granted waivers to collectively bargain.

Conclusion

Healthcare is a complicated industry with many players. A competitive cost-effective industry is beneficial to the economy and society. In an era of legislative gridlock, the antitrust regulators are in a strong position to positively impact the healthcare system. Enforcement actions when used properly to stimulate and preserve competition can lower costs and improve quality. When used improperly, the result can be the opposite.

In order to meet the FTC goal of preserving competition, antitrust regulations need to adapt to the changes of the healthcare marketplace. This can be most easily accomplished by modification of the procompetitive standards that need to be met under the rule of reason analysis. By adapting the rule of reason analysis to take into consideration the specific nature of the broader market, including troubled markets, physician shortages and the shifting demographics of provider markets, this can become a powerful tool in advancing the goals of the FTC to contain costs, improve quality, and encourage innovation. Hopefully this article will stimulate interest and dialog into the powerful role that policy-driven antitrust enforcement can play in healthcare reform.

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1 Available at https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.
2 See St. Alphonsus Med. Ctr. v. St. Luke’s Health Sys., No. 14-35173 (9th Cir. 2015) and FTC v. Advocate Health Care Network, No. 16-2492 (7th Cir. 2016). In St. Alphonsus St. Luke’s hospital acquired the Saltzer Medical Group in Nampa, Idaho and acquired over 80% of the primary care market, raising prices above competitive prices with insurance companies. The federal district court ordered St. Luke’s to fully divest itself of Saltzer’s physicians and assets. The Ninth Circuit affirmed the district court ruling. FTC v. Advocate involved a proposed merger of the two largest hospital systems in the North Shore suburb of Chicago. The merger would have created a system with a 55% market share; the next largest competitor would have had a 15% market share. The FTC action blocked the merger and prevented its anticompetitive effects.


5 Id.

6 Schneider, E., Provider Mergers: Will Patients Get Higher Quality or Higher Costs?, Commonwealth Fund Nov. 2015.


9 Id.

10 Cases 1:12-CV-00560-BLW (lead case) and 1:13-CV-00116-BLW (St. Luke’s FDC). https://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa. The federal district court held that the acquisition violated Section 7 of the Clayton Act and the Idaho Competition Act. See also supra, n. 2.


12 Section 1. Trusts, etc., in restraint of trade illegal; penalty. Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,00,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court. Section 2. Monopolizing trade a felony; penalty. Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,00,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

13 §7 Clayton Act, 15 U.S.C. § 18, Acquisition by one corporation of stock of another

No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

No person shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or a part of the assets of one or more persons engaged in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition of
stocks or assets, or of the use of such stock by the voting or granting of proxies or otherwise, may be substantially
to lessen competition, or to tend to create a monopoly.

14 Id.
15 Sec. 45. Unfair methods of competition unlawful; prevention by Commission (a) Declaration of unlawfulness;
power to prohibit unfair practices; inapplicability to foreign trade: (1) Unfair methods of competition in or affecting
commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful. (2)
The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except
banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in
section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air
carriers subject to part A of subtitle VII of title 49, and persons, partnerships, or corporations insofar as they are
subject to the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 et seq.), except as provided in section
406(b) of said Act (7 U.S.C. 227(b)), from using unfair methods of competition in or affecting commerce and unfair
or deceptive acts or practices in or affecting commerce.
16 Minnesota Rural Health Cooperative C-4111, FTC File No.0510199 (final order issued December 28, 2010).
17 Id.
19 Id.
20 Id.
21 U.S v. Alston, 974 F.2d 1206 (9th Cir.1992).
22 Id.
23 Id.
24 Id.
25 Id.
26 Id.
27 Southwest Health Alliance Inc, d/b/a BSA Provider Network, C-4327, FTC File No. 0910013 (final order July 8,
2011).
28 Roaring Fork Valley Physicians IPA, Inc., C-4288, FTC File No. 0610172 (final order issued April 5, 2010).
29 Boulder Valley Individual Practice Association, C-4285, FTC File No. 0510250 (final order issued April 2, 2010).
30 Independent Physician Associates Medical Group, Inc. dba AllCare IPA, C-4245, FTC File No. 0610258 (final order
issued February 2, 2009).
31 The court in North Texas Specialty Physicians held that a violation of the FTC Act is equivalent to a violation of
the Sherman Act. North Texas Specialty Physicians v. FTC, 528 F.3d346 (5th Cir. 2008). This is important because all
legal precedents in antitrust cases that apply to Sherman Act Violations also apply to Section 5 FTC Act violations.
32 See supra n. 28.
33 Abbreviated or "quick-look" analysis is appropriate when an observer with even a rudimentary understanding of
economics could conclude that the arrangements in question have an anticompetitive effect on customers and
markets. See, e. g., National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla., 468 U S. 85 (1984); Cal.
34 North Texas Specialty Physicians v. FTC, 528 F.3d346 (5th Cir. 2008), https://www.ftc.gov/enforcement/cases-
proceedings/0210075/north-texas-specialty-physicians-matter.
35 Id.
36 Id.
37 Id. at 353.
40 North Texas Specialty Physicians v. FTC, 528 F.3d346, 364 (5th Cir. 2008).
41 See, e.g., In the Matter of San Juan IPA, Inc., Docket No. C-4142 (consent order issued June 30, 2005),
http://www.ftc.gov/opa/2005/07/fyi0548.htm; In the Matter of New Millennium Orthopaedics, LLC, Docket No. C-
4140 (consent order issued June 13, 2005), http://www.ftc.gov/opa/2005/06/fyi0543.htm; In the Matter of White
Sands Health Care System, L.L.C, Docket No. C-4130 (consent order issued Jan. 11, 2005),
http://www.ftc.gov/opa/2005/01/fyi0504.htm; In the Matter of Piedmont Health Alliance, Inc., Docket No. 9314

42 The court also held that a violation of Section 5 of the FTC Act is the same as a violation of the Sherman Act.
43 See supra, n. 40.
44 Minnesota Rural Health Cooperative C-4111, FTC File No.0510199 (final order issued December 28, 2010).
45 Id.
46 Id.
47 Id.
48 Id.
49 Analysis of Agreement Containing Consent Order to Aid Public Comment, C-4111, FTC File No.0510199.
50 Section 5 of the FTC Act, which makes unfair methods of competition unlawful.
51 See supra n. 49 at 6-7.
52 In an example of state action doctrine, subsequent to this ruling the state of Minnesota changed the Minnesota Healthcare Cooperative Act, (Minn. Statutes 2018 62R.01-09) and took over antitrust supervision of healthcare cooperatives in Minnesota. Unlike the federal statute, the state Cooperative Act has a conditional approval option and appears to work with the organizations to help them restructure to comply with the statute. MRHC is active and it is unclear whether it is because the Minnesota law is less restrictive, the business model of MHRC has changed or a combination of both.
53 Cooperativa de Medicos Oftalmologicos de P.R. C4603, FTC file no 1410194 (final order issued February 27, 2017). In this case MCS Advantage, the Medicare Advantage Plan, contracted with a second entity, Eye Management, at a capitated rate to provide ophthalmologic care in Puerto Rico.
54 Id.
55 Id.
58 Id.
59 Id.
61 Id.
62 Id.
63 Id.
64 Id.
65 Id. Note that a joint boycott is a violation per se and therefore not subject to any further analysis. This is problematic, because the specific circumstances that precipitated the Cooperativa’s joint boycott may have necessitated the action under the circumstances. This could be remedied by taking a broader or different look at the consequences of monopsony action by the payor regarding the hardships being endured by the physicians on the Island and its effect on healthcare delivery in Puerto Rico.
67 See supra n. 57.
68 Available at https://mshp.mountsinai.org/.
69 For four years the author has served on the Board of Managers of this IPA and prior to that on the Network and Contracting Committee of the Continuum IPA that preceded MSHP. He has seen and has experienced firsthand the complexity, cost and length of the process before this IPA became operational.
70 The term “HHI” means the Herfindahl–Hirschman Index, a commonly accepted measure of market concentration. The HHI is calculated by squaring the market share of each firm competing in the market and then
summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 \((30^2 + 30^2 + 20^2 + 20^2 = 2,600)\). See https://www.justice.gov/atr/herfindahl-hirschman-index.
Big Data as a Big Source of Healthcare Fraud Prosecutions – and Defenses
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As most healthcare providers know, hardly a day goes by without the Department of Justice (DOJ) announcing a new flashy healthcare fraud settlement or conviction. And many of these splashy press releases explicitly cite the use of data and data mining as a way of identifying and prosecuting the alleged wrongdoer.¹

In fact, even when it comes to the healthcare crisis du jour — the opioid crisis — the DOJ proudly boasts of its data-mining efforts. As former Attorney General Jeff Sessions barnstormed across the country promoting the DOJ’s opioid initiative last year, he developed a standard stump speech. In that often-repeated speech, he proudly promoted a new DOJ initiative known as the Opioid Fraud and Abuse Detection Unit, a new data analytics program that focused on opioid-related healthcare fraud. In his words, this unit was using data and data-mining techniques in order to “tell us important information – who is prescribing the most drugs, who is dispensing the most drugs, and whose patients are dying of overdoses.”²

Whether it’s opioids or any other healthcare investigation, the government is increasingly using data to identify cases, develop strategies for investigation and prosecution, and tell the story to jurors.³ Increasingly, attorneys — both within and outside of government — are understanding the importance of data and are developing strategies to use healthcare data as both a sword and a shield.

This article analyzes the background of data mining in healthcare fraud prosecutions, highlights several practical high-profile fraud cases built on data, and offers practical advice for healthcare providers on using data as both a proactive compliance tool and a powerful defense after an investigation has commenced.

Background Regarding Data Mining in Government

The concept of data mining is not new. For years, private industry has been using sophisticated algorithms and software to mine large sources of data to identify patterns and highlight trends. From education to construction to non-profits, data mining has been utilized to make sense of vast arrays of information.⁴ Now, the government is catching up — particularly in the healthcare fraud enforcement space.

With respect to healthcare, the United States government has a vast array of data available at its fingertips. Whenever a healthcare provider submits a claim to the Medicare program, for example, the government receives dozens of pieces of information, including the patient’s name, date of birth, place of service, date of service, current procedural terminology (CPT) code and diagnosis code. These are just a few examples of data sets collected by healthcare regulators; vast systems for Electronic Health Record (EHR) data have the capacity to collect much more. The government is increasingly surveying this data to learn about trends and locate potential outliers, as discussed in further detail below.⁵

This assessment about the burgeoning role of data is reflected in the government’s own characterization of data mining. The Department of Health and Human Services (HHS) Office of Inspector General (OIG), the federal agency most directly tasked with overseeing the Medicare program, prides itself on its data analytics team. In its own words, “OIG uses Data Driven Decision Making to produce outcome focused results.”⁶ Further, OIG notes that it
“leverages sophisticated data analysis to identify and target potential fraud schemes and areas of program waste and abuse.” In fact, OIG created a Chief Data Officer position in 2015 to facilitate the creation of internal tools that increase OIG’s access to and utilization of data.

In the words of OIG’s Chief Data Officer, there is a tremendous increase and usefulness of data mining in developing possible fraud cases:

So what it really means is having high quality lead-generation for either our investigators, our auditors, our evaluators or for compliance oversight. One of two things can happen with our advanced analytics. Either the data can lead us to somebody that is potentially committing fraudulent activity or our investigators can have a hotline call where they can have a witness or a whistleblower come tell them that they suspect criminal activities happening, and we can bounce that against the data. So it's a really a combination of the data analytics and the data scientists and our statisticians and computer programmers with that field intelligence of our law enforcement agents working in the field -- that combination is very powerful.

Given this “very powerful” tool, healthcare providers and their counsel would be well-served by understanding the nuances of data analysis — and also understanding data’s limitations. Fortunately, HHS has elaborated on its use of data mining and has shared some of the key concepts that it focuses on when mining data.

**Practical Examples and Metrics of Data Mining**

Over the years, both HHS/OIG and the DOJ have articulated some of their more heavily utilized data-mining metrics. Understanding these metrics is a useful way of identifying the trends and statistics that matter to the government. Some of these metrics include:

- **Trend Tool.** Broadly defined, this tool looks at trends over time to see how providers’ prescribing and billing habits fluctuate and whether certain spikes emerge. This temporal analysis is often very critical in understanding how and when patterns change. The government frequently uses this trend analysis to see whether certain events (such as a new executive coming on board, a new financial arrangement, or other externality) affected healthcare claims.

- **Peer Comparison Generator.** The government very often compares providers to their relative peers to assess how their claims compare to others. This analysis is, of course, not dispositive, but it is highly relevant. If one doctor stands out to her peers by several orders of magnitude, this physician might find herself on a government investigation list. For example, government agents may search for physicians who prescribe higher amounts of opioids than their peers.

- **Link Analysis.** This tool examines relationships from one entity to another. For instance, the analysis might examine one physician’s relationship with a pharmacy and whether that relationship might be tainted by improper kickbacks. In this example, the government would look at both the physician and the pharmacist to determine any linkages in patients, billing patterns, and other indicators of a possibly nefarious relationship under the Anti-Kickback Statute, which prohibits the exchange of anything valuable for the referral of services payable by the government.
Payments by Geographic Area. The government assesses different regions of the country individually to determine whether there are any specific geographical spikes related to billing. Often fraud schemes are prolific in one particular geographic area. For example, certain durable medical equipment (DME) fraud might be prevalent in one region of the country but not another. By being able to focus on geographic-specific trends, the government is able to determine where best to apply resources.

Dashboards. Finally, a catch-all tool used within government is to look at a variety of metrics on one dashboard. The government is able to compare Medicare claims, billing data, prescriber employment records, and the like to determine a holistic “dashboard” view of a provider’s practice.

These metrics are just illustrative examples of how the government mines data to develop possible cases. Depending on the subject matter, the government might use more sophisticated or nuanced data. For example, in the opioid-related investigations mentioned above, the government has developed sophisticated metrics involving specific doses of drugs, and the government has compared how quickly — and how often — certain providers prescribe opioids.

As data mining becomes more prolific, one can expect that government agents and prosecutors will become increasingly adept at data mining manipulation. Accordingly, some of the tools that seem robust today will likely be primitive in the near future. Nonetheless, understanding these tools — and the government’s use of these tools — is an important way for healthcare providers and their attorneys to best stay off the government’s radar screen.

Practical Examples of Data Mining

It is useful to consider several practical examples of the government using data mining to develop specific prosecutions. These examples are meant to be illustrative of the government’s increasing sophistication with respect to data analysis.

One of the most far-reaching examples of the use of data mining was in 2015, when the government targeted an entire industry: compound pharmacies. Based on government reporting, the industry was selected for review due to an atypical and aberrant spike in billing to the TRICARE program. The government used a panoply of data tools to identify pharmacies that stood out relative to their peers. These tools included looking at trend analyses, top billing pharmacies, and pharmacies with a relatively few number of prescribers.

Another example of data mining was the recent high-profile prosecution of Salomon Melgen, M.D., a well-known ophthalmologist in South Florida and, at one point, one of the top three highest Medicare billers in the country. The case against Dr. Melgen was put to trial in 2018. The government’s case was predominantly based on data analysis and data mining. Evidence adduced at trial showed Dr. Melgen to be a significant outlier relative to his peers, including performing dozens of tests that his peers never conducted. This type of peer analysis was critical in obtaining a government verdict and the subsequent imposition of a 17-year prison sentence.

Practical Compliance Tips for Providers
In light of the government’s focus on data analysis, healthcare providers and counsel would be well-served by adapting their practices to reflect this new source of law enforcement referrals. Below are 10 practical tips to get ahead of the curve.

First, as a threshold matter, understand the emergence of data-driven analysis. Healthcare counsel need to recognize that regulators are increasingly harnessing and using the power of data to identify outliers. By understanding this focus, providers can begin the process of undertaking proactive steps to ensure maximum compliance and reduce risk.

Second, to the extent it is not done already, start to collect and store relevant data. While most healthcare providers are already collecting some data, it is a best practice to ensure that clients have a system in place to capture as much relevant data as possible. Information is power. And, in collecting data, it is important to be thoughtful about how data is collected and what data is actually being tracked. For example, in a recent study at an ophthalmology clinic at the University of Michigan, EHR data matched patient-reported data in just 23.5 percent of records. In that study, when patients reported having three or more eye health symptoms, the EHR record was inaccurate, as the database did not capture tertiary diagnoses and symptoms. Therefore, it is advisable to ensure that the EHR system being used is up to date, the work-flow process is practical and efficient, and users are accurately inputting data into the systems.

Third, educate others within the provider about the importance of data collection and data analysis. One of the most critical pieces to harnessing and leveraging the power of data is to educate employees about the importance of accurate data collection. This means teaching physicians, for example, to accurately collect data from patient encounters. It means teaching billers and coders about including all relevant fields, even if those fields might not ultimately be billed. Most practices start — with good reason — at proper collection of claims information. But a best practice is to collect more than just claims information but also relevant fields on patients’ clinical records (e.g., medications, imaging studies, lab reports), as well as other external data (e.g., prescriptions and financial information.)

Fourth, understand the importance of data cleanliness. Just like most clinicians understand the importance of cleanliness in the operating room, so too must healthcare providers understand the importance of cleanliness in data. Remember the adage of “garbage in, garbage out.” Unless the healthcare data is accurate when it is entered, it cannot be relied upon afterwards. Therefore, providers must constantly clean or scrub data to ensure that it is accurate, correct, consistent, relevant, and not corrupted. One idea is to consider the use of a data steward or an outside vendor if this cannot be accomplished internally.

Fifth, compliance counsel using data to build a case for their clients must always remember that the data is only as good as the query. In order to get a meaningful understanding of data to build a successful defense, compliance counsel needs to have access to the right data and query this data correctly. Looking at a million fields of data doesn’t mean much; it means only something in context. Thus, a best practice is to start at the end: ask what information is ultimately wanted. If counsel wants to know, for example, which providers are billing the most procedures, they would need to focus on billing data. If counsel is interested in possible suspect kickback arrangements, they would need to review billing data in concert with financial data.

Sixth, compliance counsel would be well-served by looking for trends in their client’s own data — preferably before the government does so. Some compliance counsel look at, for example, the top CPT codes being billed by clients. Looking at the utilization of these codes and
how this utilization has changed over the past few years can provide valuable leads and can likely lead to fruitful conversations with clients. For example, compliance counsel should identify top outlier physicians and ask clients, such as hospitals or employers, why certain outlier physicians are so far ahead of their peers. Likewise, counsel should study top referrers and help their clients make sure they can explain why certain referrers stand out. Ultimately, counsel must be able to explain changes or variances because when they are significant, the government is likely to ask questions.

Seventh, many providers are beginning to gather not only their client’s data, but also their peers’ data and doing their own comparisons. As mentioned above, the government is increasingly comparing providers to their peers. While providers typically do not have access to others’ data to do this type of analysis, there are ways to use open-source data to approximate this type of comparison. Thus, where appropriate, it is useful to examine open sources for data and to aggregate this data to develop a complete picture of where providers and individuals stand relative to others.

Eighth, it is a best practice to combine data sets to get a full picture. Looking at data in a vacuum is unhelpful. Looking at, for example, the total reimbursement of a client and ignoring other data, such as the client’s patient population mix or fair market payments to/from other providers, does not reveal much. Those providers that are most effectively harnessing data as a sword and shield are looking at the complete picture of data available. This means, as a practical matter, synthesizing and visualizing data across different data sets. A best practice is to catalogue all available data sets and then determining how these databases can overlap with one another.

Ninth, it is vitally important to update a provider’s data periodically. Data in healthcare, like all of healthcare, is not static — it constantly changes. For instance, a patient may update his/her address or may update his/her prescription medications. Therefore, understand what data requires updating and schedule ticklers to ensure that data is being updated.

Tenth, always remember the Health Insurance Portability and Accountability Act (HIPAA). HIPAA’s protections and mandates apply to aggregated data, just like it applies to individual files. Therefore, follow the HIPAA security requirements, such as authentication protocols and control over access to protect the data. One best practice is to consider housing a de-identified data set. The benefit of this is that it removes the patient identifiers and, therefore, might be exempt from HIPAA’s mandates. This might allow for easier access in manipulating and analyzing the data.

Using Data When the Government Asks Questions

Inevitably, no matter how much proactive compliance is done, many healthcare providers will face the scrutiny of government regulators. Most do not need a reminder that healthcare is an incredibly regulated industry and that regulators will likely ask questions.

Therefore, healthcare providers would be well-served by not panicking when the inevitable government subpoena (or request for information, such as a Civil Investigative Demand) arrives but taking the scrutiny seriously. When the government asks questions, a few basic pointers are critical: (a) preserve all documents and all data; (b) ensure proper internal reporting; and (c) try to determine the focus of the government investigation from the subpoena
or otherwise. These concepts are, admittedly, self-evident for most healthcare providers, but they are nonetheless critical threshold steps.

While these reminders are somewhat axiomatic, thinking critically about data on the front end in responding to government inquiries is less obvious. Data can be a powerful response to a government investigation. Remember that data is not just helpful with respect to proactive compliance; it is also helpful in rebutting a governmental inquiry.

Increasingly, providers recognize that, once the government’s focus becomes clear, looking at the target’s data is critical. Using this data — and presenting it in a favorable light — can be very helpful to negate the government’s assumptions. For example, data can be used to negate scienter by showing that an anomaly was just that — a one-off, rather than a broader practice. And, for those cases that cannot be resolved before litigation is initiated, data is a very helpful tool to illustrate a defendant’s perspective at trial.

Conclusion

The emergence of data analytics is changing business as usual across all industries, and the government healthcare enforcement space is no exception. By understanding the government’s focus on data analytics, and by implementing practical suggestions to use data as both a proactive compliance tool and a reactive defense, healthcare clients can better prevent themselves from government scrutiny. An ounce of prevention is worth a pound of cure. Investing in good data analysis techniques today can prevent or mitigate a series of inquiries later.

Jason Mehta is a partner at Bradley Arant Boult Cummings, LLP in Tampa, Florida. He formerly was a federal prosecutor focusing on healthcare fraud. During his five years at the Department of Justice, he recovered more than a quarter of a billion dollars and prosecuted dozens of white-collar executives. He now advises individuals and corporations in both civil and criminal DOJ inquiries and investigations. He may be reached at jmehta@bradley.com.

1 See, e.g., United States Settles False Claims Act Allegations Against Jacksonville-Based Fertility, available at https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-jacksonville-based-fertility (“This case was developed by proactively mining healthcare reimbursement data. In mining through this data, the Center was identified as a top biller of fertility related treatments. In addition, through this data mining, government investigators were able to determine that the Center had billed for services allegedly rendered by Dr. Fox – the owner of the practice – even when he was out of the country.”); see also Four Area Hospitals Pay Millions to Resolve Ambulance Swapping Allegations, available at https://www.justice.gov/usao-sdtx/pr/four-area-hospitals-pay-millions-resolve-ambulance-swapping-allegations (“Among the tools instrumental to the settlement were those provided by HHS-OIG’s Chief Data Office, Consolidated Data Analysis Center (CDAC). CDAC provides HHS-OIG and its law enforcement partners with best practices, consultancy and skills development in data mining, predictive analytics and data management and modeling in support of fraud prevention and recovery.”)


While this article details the federal government’s data mining in healthcare, data mining is not unique to federal regulators. In fact, increasingly state regulators and private insurers are doing their own data mining to identify suspicious claims and trends. And increasingly the federal government is using these data analytics from third parties as investigative leads. See Claims Data and Health Care Fraud: The Controversy Continues, available at https://www.forbes.com/sites/insider/2012/09/25/claims-data-and-health-care-fraud-the-controversy-continues/#4b9b914221f0 (noting increased use of data mining and partnerships between the federal government and private payors).


Id.


By way of an illustrative example, South Florida has long had a unique issue with various forms of alleged durable medical equipment fraud and the DOJ has, accordingly, devoted resources specifically to this problem. The resources devoted to the Southern District of Florida are different from those devoted to other geographic regions where a HEAT strike force team is deployed.


United States Settles False Claims Act Allegations Against Compound Pharmacy Owner For $4.25 Million, available at https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-compound-pharmacy-owner-425 (noting “This case was developed through an initiative to track and prosecute compound pharmacies that submitted millions of dollars in improper claims to the TRICARE program. The government estimates that up to $2 billion of tainted and unnecessary compound prescriptions had been submitted to and paid by the government. In the Middle District of Florida, the government has recovered almost $70 million in fines and penalties over the past 18 months.”)

15 See Completeness of Electronic Dental Records in a Student Clinic: Retrospective Analysis, Seth Aaron Levitin, BSc; John T Grbic, DMD; Joseph Finkelstein, MD, PhD, JMIR Med Inform 2019;7(1):e13008 doi:10.2196/13008, available at https://medinform.jmir.org/2019/1/PDF.

16 For example, providers can access open-source data from the following sources: (1) data.cms.gov; (2) www.healthdata.gov; and (3) https://graphics.wsj.com/medicare-billing.


18 45 C.F.R. Parts 160, 164.
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We place particular importance on regional member participation because the nation’s healthcare is regional in its organization and delivery. As a unique member-driven group, we depend on the support and commitment of this nation’s most influential health law attorneys. Our members are among the most experienced and dedicated health law practitioners in the country, serving in a wide variety of roles and commonly united in the pursuit of professional excellence. We tackle the toughest and most demanding health law issues by drawing upon our members’ diverse professional experiences and richly varied viewpoints. Our leading educational programs, policy activities and definitive publications rely upon our members’ commitment and engagement. We therefore recognize their dedication through this annual regional listing of the firms with the largest number of members in 2018 as reported to the ABA.

**2018-2019 YEAR IN REVIEW**

<table>
<thead>
<tr>
<th>Members</th>
<th>Lawyers</th>
<th>Associates</th>
<th>Law Students</th>
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<tr>
<td>10,404</td>
<td>7,235</td>
<td>324</td>
<td>2,845</td>
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</tbody>
</table>

Age Breakdown* (%)
- 30 & under: 5
- 31-40: 16
- 41-50: 20
- 51-60: 26
- 62-70: 24
- 71 & over: 9

Gender* (%)
- Male: 49
- Female: 46
- Non-Binary/3rd Gender: 5

Practice Areas* (%)
- Business & Transactions: 14
- Litigation & Risk Management: 12
- Fraud & Compliance: 11
- Physician Issues: 10
- eHealth, Privacy & Security: 10
- Facility Operations: 9
- Managed Care & Insurance: 9
- Payment & Reimbursement: 9
- Life Sciences: 7
- Public Health & Policy: 6
- ADR & Conflict Management: 5
- Allied Professionals: 5
- Post-Acute Care: 5

Practice Settings* (%)
- Private Practice: 70
- In-House: 22
- Government/Judicial/Military: 4
- Academic/Legal Publishing: 3
- Other: 1

Health Lawyer Circulation .......... 16,800+
(Published bi-monthly: 6 times annually)

Health eSource Circulation .......... 9,000
(Published monthly: 12 times annually)

HLbytes Circulation .................. 9,000
(Published weekly: 46 times annually)

National Conferences ............... 5
- Washington Health Law Summit
- Emerging Issues in Healthcare Law
- Healthcare Fraud
- False Claims Act and Qui Tam Trial Institute
- Physicians Legal Issues

Distance Learning Events .......... 52
- Total CLE Hours: 78
- Total CLE Credits Earned: 15,000
- Average Registrants Per Event: 110

*Based on known lawyer members.
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mintz.com  
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nixonpeabody.com  
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venable.com  
Practice Head: Thora A. Johnson

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riker.com  
Managing Partner: Glenn A. Clark

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   Practice Head: Molly K. Marcum

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   Suite 1300
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   Phone: 208.562.4900
   parsonsbehle.com
   Practice Head: J. Kevin West

10. Latham & Watkins LLP
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    Suite 100
    Los Angeles, CA 90071-1560
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    Practice Heads: Daniel Meron and Daniel K. Settelmayer


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**UPCOMING EVENTS**

17th Annual Washington Health Law Summit  
December 9-10, 2019  
The Ritz-Carlton  
Washington, DC

21st Annual Conference on Emerging Issues in Healthcare Law  
March 11-14, 2020  
Manchester Grand Hyatt Hotel  
San Diego, CA

Physicians Legal Issues Conference  
September 2020  
Chicago, IL

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