



Health Law Developments

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From the Chair

Dear Health Law Section Members,

The Executive Committee has been busy planning many activities on behalf of the Section this year and we are excited about our upcoming events.

The Section recently sponsored the Fundamentals of Health Law Program. Thanks again to Program Chair Rod Meadows along with everyone who participated for another successful program.

The Section is also hosting a Special Lunch Program on Tuesday, April 18 from 11:30 a.m. to 1:30 p.m. at Alston & Bird regarding the latest on health law reform. We hope that you will be able to join us.

Additionally, the Executive Committee is currently planning the annual Advanced Health Law Program, which will be held in the Fall and cover a wide range of current health law topics. Please be on the look-out for future notices regarding this program and other upcoming events from the Section.

For this Spring 2017 Health Law Section Newsletter, we would like to thank all of the authors for their thoughtful contributions.

We also would like to thank the Executive Committee members Keri Conley, Amy Fouts and Rebecca Merrill for their leadership and time spent recruiting authors and editing and publishing the newsletter.

The Executive Committee strives to prepare meaningful, substantive programs for the Section and provide members with information relevant to the practice of health law in Georgia. We invite you to submit articles, reports, and proposals for presentations that would be informative to the membership.

It is an honor to serve as Chair of the Health Law Section this year. Please let me know if you have any ideas or suggestions that might help us continue to work in the right direction and better serve you.

Best regards,
Keith Mauriello,

Using the DOJ Fraud Section Guidance on “Evaluation of Corporate Compliance Programs” to Enhance Compliance Plans

by Thomas William Baker¹

A well-functioning Compliance Program is an absolute best practice for health care providers and suppliers and other entities that involve governmental reimbursement programs. While there are no existing legal requirements for such programs (with the exception of skilled nursing facilities), multiple federal agencies have published guidelines for structuring Corporate Compliance and Ethics Programs for many years. However, until now there has been little guidance on how a Compliance Plan is expected to operate.

On Feb. 8, 2017, the Fraud Section of the U.S. Department of Justice (DOJ) quietly and without any accompanying press release published comprehensive guidance on the “Evaluation of Corporate Compliance Programs” (referred to herein as the “DOJ Compliance Program Guidance”) on the “Compliance Initiative” page of the DOJ web site: <https://www.justice.gov/criminal-fraud/page/file/937501/download>. Rather than state precisely how a Corporate Compliance and Ethics Plan should be constructed, the DOJ presents a series of questions that DOJ internally asks when assessing whether an organization that is under investigation for potential misconduct has effectively implemented its Compliance Program.

Importance of Implementing an Effective Compliance Program.

Whether an organization has an effective Compliance Program is critically important when allegations of wrongdoing arise because implementation of an effective Compliance Program is potentially exculpatory and is also valuable when an organization is engaged in settlement negotiations with federal agencies. Consequently, when confronted with an allegation of misconduct, the typical initial response from the target organization is “we have a Corporate Compliance Program.” However, to the DOJ, merely making that statement or even showing the DOJ a document that appears appropriate is not enough: the DOJ needs to determine whether the Compliance Program is in fact effectively implemented.

The DOJ Compliance Program Guidance Complements Other Compliance Guidance.

The DOJ identifies eleven topics for a focused Compliance Program review, each of which is followed by a series of specific questions for evaluation of the Compliance

Program’s effectiveness. Most of these topics and the related questions dovetail neatly with the Federal Sentencing Guidelines as well as Compliance Guidelines promulgated by other governmental agencies such as the United States Department of Health and Human Services, Office of the Inspector General (OIG) and statutory requirements of skilled nursing facility Compliance and Ethics Programs enacted through Section 6102 of the Affordable Care Act of 2010 (which for convenience are collectively described as the “Compliance Program Guidelines”).

The Guidelines for Organizational Defendants from the Federal Sentencing Guidelines form the foundation for all Corporate Compliance and Ethics Programs and describe seven specific elements that must be set forth in every Corporate Compliance Plan:

- **Standards of Conduct.** The organization must establish specific ethical standards and policies and procedures to be followed by all of its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.
- **Responsibilities.** Specific individuals at a high-level within the organization must be assigned overall responsibility to oversee compliance with such standards and procedures.
- **Delegation of Authority.** The organization must use due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities.
- **Communication/Education.** The organization must take steps to communicate effectively its standards and procedures to all employees and other agents by, for example, requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.
- **Monitoring and Auditing.** The organization must take reasonable steps to achieve compliance with its standards by, for example, instituting monitoring and assessment systems reasonably designed to detect misconduct by its employees and other agents and by having in place and publicizing a reporting system through which employees and

other agents can report misconduct by others within the organization without fear of retribution.

- **Discipline.** The standards must be consistently enforced through proper disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.
- **Response and Prevention.** After an offense has been detected, the organization must take all reasonable steps to respond appropriately to the offense and to prevent future similar offenses, including any necessary modifications to its compliance program to prevent and detect violations of law.

Within the context of these seven elements, the size and complexity of the organization dictates the formality of the Compliance Plan.

In addition, the DOJ Compliance Program Guidance reflects the growing emphasis on identifying individual persons who are involved in the compliance process as first expressed in the “Yates Memo” issued by former Deputy Attorney General Sally Yates that, in essence, directs the DOJ to identify potentially culpable individuals as part of any DOJ investigation of an organization.

To put the DOJ Compliance Program Guidance into perspective, the Compliance Program Guidelines are prophylactic in nature and address what an organization should do to prevent allegations of wrongdoing, and the DOJ Compliance Program Guidance describes how the DOJ determines whether the organization has in fact implemented an effective Compliance Program after an allegation of misconduct arises.

Summary of DOJ Compliance Program Guidance In the Context of Other Compliance Program Guidelines.

Overall, the topics and questions that DOJ uses when evaluating the effectiveness of a Corporate Compliance Program are much more focused and detailed than the seven core requirements of a Corporate Compliance and Ethics Plan as described in the Federal Sentencing Guidelines and much more process oriented than substantive compliance guidance promulgated by agencies like the OIG. The following is a summary of some key points of DOJ emphasis in its Compliance Program Guidance on each of the DOJ’s eleven topics within the context of the Compliance Program Guidelines:

- **Analysis and Remediation of Underlying Misconduct.** The questions under this topic relate to the Compliance Program Guidelines requiring organizations to “respond” to allegations of misconduct and take actions to “prevent” further similar offenses and include inquiries regarding the following: the cause of the misconduct and whether the response revealed “systemic issues” (in contrast to an isolated incident); who made the analysis; and whether there were prior opportunities to detect the misconduct, and, if so why the opportunities were missed.

- **Role and Involvement of Senior and Middle Management.** The questions under this topic relate to the Compliance Program Guidelines requiring specific high-level personnel to have overall responsibility for implementing the Compliance Program and include inquiries regarding the following: whether senior leaders have demonstrated leadership in the organization’s compliance and remediation effort and what specific actions senior leadership has taken in that regard; what compliance expertise has been available on the board of directors; whether the board of directors have held executive or private sessions with the compliance and control functions; and what types of information the board of directors and senior management examined in their oversight of the area in which the misconduct occurred.
- **Autonomy and Resources.** The questions under this topic relate to the Compliance Program Guidelines requiring communicating compliance standards and procedures to all employees and other agents as well as requiring specific high-level personnel to have overall responsibility for implementing the Compliance Program and include inquiries regarding the following: whether compliance representatives were involved in training and decisions relevant to the misconduct; how the compliance function compares with other organizational functions in stature, compensation, and access to key decision makers; whether compliance personnel were properly qualified; whether the compliance officers had direct reporting lines to the Governing Board; how the organization insures independence of the compliance function; how the organization has responded to prior allegations of misconduct presented to senior management by the compliance officers; whether the compliance department received proper funding and resources; and whether the organization outsourced the compliance function to an external firm or consultant and if so how that decision was both made and managed.
- **Policies and Procedures.** The questions under this topic relate to the Compliance Program Guidelines requiring standards of conduct and communicating the standards of conduct to the organization’s agents and include inquiries regarding the following: the process for designing and implementing policies and procedures; how the organization manages accountability for supervisory oversight of performance in accordance with the standards of conduct; how the standards of conduct were communicated to the organization’s agents; who was responsible for integrating the standards of conduct into the organization’s operations; why the Compliance Program failed to detect and prevent the misconduct; how the misconduct was funded and whether the

organization had effective internal controls; and, if vendors were involved in the misconduct, the process for vendor selection.

- **Risk Assessment.** The questions under this topic relate to the Compliance Program Guidelines requiring a baseline assessment of regulatory risk and include inquiries regarding the following: the methodology that the organization used to identify, analyze, and address its particular regulatory risks; and what information and metrics the organization used to help detect the misconduct in question.
- **Training and Communications.** The questions under this topic relate to the Compliance Program Guidelines requiring effective communication of the Compliance Program standards and procedures to all employees and other agents and include inquiries regarding the following: whether the organization provided tailored training for high-risk and control employees that address the risk in the area where the misconduct arose; how the organization measured the effectiveness of the training; what senior management has done to let employees know the organization's position on the misconduct; what communications are generally made when an employee is terminated for failure to comply with the organization's standards of conduct; what resources are available to employees to provide guidance regarding compliance policies; and if the organization has assessed whether its employees know when to seek advice and if they would be willing to do so.
- **Confidential Reporting and Investigation.** The questions under this topic relate to the Compliance Program Guidelines requiring response to allegations of misconduct and preventing further similar offenses and include inquiries regarding the following: how the organization collected, analyzed, and used information from its compliance reporting mechanisms; how the organization insured that investigations were independent, objective, appropriately conducted, and properly documented; and the process for responding to investigative findings and how high up in the organization the investigative findings are reported.
- **Incentives and Disciplinary Measures.** The questions under this topic relate to the Compliance Program Guidelines requiring consistent enforcement of Compliance Program policies and procedures through appropriate disciplinary mechanisms and include inquiries regarding the following: when and how disciplinary actions in response to the misconduct were taken; whether managers were held responsible and disciplinary measures were considered for misconduct that occurred under their supervision; whether the organization has ever terminated or disciplined any person for similar misconduct; who participated in making disciplinary decisions; whether disciplinary actions have been consistently and fairly applied; and whether the organization has incentivized engaging in compliant and ethical conduct.
- **Continuous Improvement, Periodic Testing and Review.** The questions under this topic relate to the Compliance Program Guidelines requiring monitoring and auditing the effectiveness of the Compliance Program and include inquiries regarding the following: what kind of audits would have revealed the misconduct before it occurred, were those audits conducted, and what were the findings of any such audit; how has audit information been reported to senior management; how often are internal audits generally conducted in high risk area assessments; what control testing has the organization generally undertaken; and how often has the company updated its risk assessments and reviewed its compliance policies, procedures, and practices.
- **Third Party Management.** The questions under this topic relate to the Compliance Program Guidelines requiring delegation of authority for implementing the Compliance Program to qualified persons when an organization's operations have an independent, third party management company and include inquiries regarding the following: how the organization's third party management process has corresponded to the nature and level of the enterprise risk identified by the organization; whether this process has been integrated into the relevant procurement and vendor management process; the business rationale for using a third party management company; what mechanisms the organization used to insure that the third party management company contract terms specifically describe the services to be performed and have appropriate payment terms, the described contractual work is actually performed, and that compensation is commensurate with the services rendered; how the organization analyzed the third party's incentive model against compliance risks; how the organization monitors third party management performance; how the organization has trained the relationship managers about what the compliance risks are and how to manage them; how the organization has incentivized compliance and ethical behavior by third party management companies; whether red flags were identified from the due diligence of the third parties involved in the misconduct and how they were resolved; whether a similar third party has been suspended, terminated, or audited as a result of compliance issues; and how the company has monitored situations to insure that compliance issues related to vendor relationships do not arise again.
- **Mergers and Acquisitions.** The questions under this topic relate to review of the compliance function in a specific setting and do not precisely fall into the requirements identified in the Compliance

Program Guidelines and include inquiries regarding the following: whether the misconduct or risk of misconduct was identified during due diligence; how the risk assessment due diligence was conducted and who individually conducted it; how the compliance function has been integrated into the merger, acquisition, or integration process; what has been the organization's process for tracking and remediating misconduct identified in due diligence; and what has been the organization's process for implementing compliance policies and procedures at new entities.

Using the DOJ Compliance Program Guidance for Self-Assessment.

Organizations now have a detailed template for understanding how the DOJ assesses existing Compliance Programs when there is an allegation of wrongdoing. It is therefore advisable for all organizations to engage in a self-assessment of the effectiveness of their Compliance Programs using the DOJ Compliance Program Guidance as a baseline for how Compliance Programs are expected to perform.

Reflecting on the content of this analytical framework, we see the following themes:

- **Senior Management Must Be Actively Involved In Supervision of the Compliance Process.** When an allegation of misconduct arises, DOJ can make senior management accountable, even if senior management is not directly involved in the alleged misconduct. This is consistent with both the "Responsible Office Doctrine" that has long been part of federal False Claims Act law and the "Yates Memo" that focuses on making individuals responsible for corporate acts.
- **The Compliance Function Must Have the Ability to Report Directly to the Governing Board.** This addresses the concern expressed in the Compliance Program Guidelines that compliance concerns reported to compliance officers through the organization's internal reporting system might be blocked by senior management (such as the chief financial officer, general counsel, or chief executive officer), whose performance may be implicated in the report.
- **Compliance Expertise Must Be Made Available to the Governing Board.** The Governing Board must actively oversee implementation of the organization's Corporate Compliance and Ethics Plan. This is consistent with the standard of conduct for directors of Delaware corporations established in *In re: Caremark International, Inc.* which, in essence, provides that directors may be exposed to individual liability for breach of the duty of care if the organization fails to implement a Corporate Compliance and Ethics Plan that satisfies the seven elements described in the Federal Sentencing Guidelines for Organizational Defendants.²
- **DOJ Distrusts Independent Contractors.** In general, federal regulatory agencies believe

that there is more opportunity for misconduct through independent contractor arrangements than there is through bona fide employees, and the DOJ Guidance is consistent with that belief. For example, it is perfectly permissible for an organization to outsource the compliance function to an independent contractor, but, if so, then how and why that decision was made and how it was managed must be explained. This leads back to informed decision making by the Governing Board. Also, the DOJ dedicates an entire topic to Third Party Management, demonstrating that DOJ perceives third party management as a regulatory vulnerability. Although third party management agreements are also perfectly permissible, they are subject to intensified scrutiny when an allegation of misconduct arises. Once again, responsibility for oversight of the third party management agreement and accountability of third party vendors in general falls on the organization's Governing Board.

- **The Organization Is Expected to Engage in Continuous Self-Critical Analysis and Regulatory Risk Assessment.** A Corporate Compliance and Ethics Plan cannot be a static piece of paper filed in a notebook in the organization's bookcase: it must become a living, breathing part of the organization. Resources must be allocated for active management of the compliance function and periodic assessment to identify potential regulatory risk.

Every organization now has a blueprint for understanding how the DOJ will assess an organization's compliance efforts when there is an allegation of misconduct. How would your Compliance Program hold up to this scrutiny?

If you want additional information, please contact Tom Baker at (404) 221-6510 or tbaker@bakerdonelson.com.

(Endnotes)

- 1 Tom Baker, a shareholder in the Atlanta Office of Baker Donelson, is a member of the firm's Health Law Group.
- 2 *In re Caremark Intern. Inc.* Derivative Litigation, 698 A.2d 959, 2 EXC 21 (Del. Ch. 1996).

The opinions expressed within *Health Law Developments* are those of the authors and do not necessarily reflect the opinions of the State Bar of Georgia, the Health Law Section or the Section's Executive Committee.

MACRA: 2017 Transition Year and Beyond

by Barbara Rogers

According to the Centers for Medicare and Medicaid (CMS), over 55 million Americans receive services under Medicare Part B¹, and the clinicians who provide those services are well into the first year of data collection under CMS' new payment system.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)², bipartisan legislation that was finalized in October 2016 and effective Jan. 1, 2017, replaced the 1997 Medicare Sustainable Growth Rate (SGR) methodology related to the Physician Fee Schedule. The new reimbursement approach under MACRA, entitled the Quality Payment Program (QPP), intends to replace the SGR formula with a more predictable payment method that shifts payments from volume and rewards value and quality outcomes.

Quality Payment Program

The QPP consists of two pathways for provider participation: (i) the Merit Based Incentive Payment System (MIPS), designed for providers in traditional, fee-for-service Medicare; and (ii) the Advanced Alternative Payment Model (Advanced APM), designed for providers who participate in specific value-based care models. CMS predicts that anywhere between 592,000 and 642,000 clinicians in the 2017 performance year will be subject to MIPS, making MIPS the "default" payment program for most Part B providers.³ Clinicians who are exempted from participation in MIPS, but would otherwise meet eligibility requirements, fall into three groups:

1. First year Medicare Part B participants
2. The clinician falls below the low-volume threshold⁴
3. Qualified Advanced APM participants

For QPP purposes, a clinician is currently defined as a physician⁵, physician assistant, nurse practitioner, clinical nurse specialist, and certified registered nurse anesthetist. In 2019, the types of Medicare Part B eligible clinicians are anticipated to expand to include physical or occupational therapists, speech-language pathologists, audiologists, nurse midwives, clinical social workers, clinical psychologists, and dietitians. The QPP does not apply to facilities or hospitals.

During the 2017 transition year, the QPP allows clinicians to "pick your pace" as it relates to performance data collection. Some providers began collecting performance data on January 1, 2017, while others have chosen to start collecting data sometime after January 1, with collection dates being able to start up until October 2, 2017. Regardless of when the clinician begins the data collection, all 2017 performance data must be submitted to CMS by March 31, 2018.

The Merit-Based Incentive Payment System

The affected clinicians who will participate in the MIPS program are called "MIPS eligible clinicians," and, as noted above, the types of clinicians eligible for participation in MIPS are currently narrowly defined, but expected to expand in the future.

Three existing and increasingly familiar programs were consolidated to create MIPS – (i) the Physician Quality Reporting System (PQRS), (ii) the Physician Value-Based Payment Modifier (VM), and (iii) the Medicare Electronic Health Record Incentive Program for Eligible Professionals (Meaningful Use). Participants within MIPS will earn a payment adjustment based upon evidence-based and practice-specific quality data, similar but simpler than what was previously required. This data will be weighted across four performance categories, creating a composite performance score (CPS), on a 0 to 100 point scale. The four categories, and the respective 2017 performance year/2019 payment year weights, are:

- Quality (replaces PQRS; weighted at 60 percent)
- Improvement Activities (new category; weighted at 15 percent)
- Advancing Care Information (replaces Meaningful Use; weighted at 25 percent)
- Cost (replaces VM)⁶

MACRA indicates that MIPS eligible clinicians are impacted financially in two ways – (i) a minimal annual inflationary adjustment to the Part B fee schedule and, (ii) MIPS value-based payment adjustments (incentives or penalties) based on the MIPS CPS. As to the latter, which is the more substantial of the two financial changes, the payment adjustments by performance year (payment year) are as follows:⁷

- 2017 (2019): + or – 4 percent
- 2018 (2020): + or – 5 percent
- 2019 (2021): + or – 7 percent
- 2020 (2022): + or – 9 percent

For MIPS eligible clinicians, the 2017 transition year allows for the following levels of participation, with the corresponding payment adjustments in 2019:⁸

- **No Participation.** If no 2017 performance data is submitted, the clinician will receive a negative 4 percent payment adjustment.
- **Minimum Amount Submitted.** If a minimum amount of 2017 data is submitted (*e.g.*, reporting

only one quality, advancing care information or improvement activity measure), the clinician can avoid a downward payment adjustment (*i.e.*, the payment will remain neutral).

- **Partial Submission.** If a clinician submits 90 days of 2017 performance data, the clinician may earn either a neutral or positive payment adjustment, with the potential to earn the maximum adjustment (*i.e.*, nothing in the QPP is designed to give 90 day reporters a lower score).
- **Full Submission.** If a clinician submits a full year of 2017 performance data, the clinician may earn a positive payment adjustment.

For each performance year, CMS will establish a performance threshold (PT) number of points whereby clinicians earning PT points receive zero percent adjustment to their Part B payments. Each additional point the clinician earns equates to a higher payment, whereas each point below the PT results in a penalty (*i.e.*, reduction in payment), until the floor is reached. The 2017 PT is set at 3 points and the “exceptional performance bonus” threshold⁹ is set at 70 points. As 2017 is the transitional year, these PTs are created to greatly reduce the likelihood of being penalized for low performance. However, starting in 2019, MACRA requires that the PT be determined annually as either the mean or median of the MIPS scores for all eligible clinicians in a prior period selected by CMS, with PTs expected to increase each year as performance improves.

MIPS participants can report as either an individual or report as a group. Reporting as an individual will result in payment adjustments based upon the individual’s performance, while reporting as a group will result in payment adjustments based upon the group’s performance¹⁰. To submit data through the CMS interface as a group, a group must register by June 30, 2017. Additionally, although MACRA provides for solo and small practices to join together as a “virtual group” and submit combined MIPS data, this QPP feature will not be available in 2017. CMS hopes to implement virtual groups in the future, as they work to obtain guidance from various stakeholders on how to structure and implement the virtual group concept.

Of particular importance for clinicians to be aware, the QPP provisions address the increasing consumer demand for more transparency in physician quality. As a result, within approximately twelve months after the end of each performance year, MIPS data will be published to the public through the CMS Physician Compare website. Consumers, for the first time, will be able to see their clinicians rated on a scale of 0 to 100, the scores for each MIPS category, and how that clinician compares to his peers nationally. Moreover, this data may impact, *inter alia*, physician recruiting, contracting, compensation, and credentialing.

Advanced Alternative Payment Models

An APM is a payment approach that provides an added incentive payment to provide high-quality and

cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. Advanced APMs are a subset of APMs and allow practices to earn more for accepting risk related to patient outcomes.

For the 2017 transition year, CMS has identified the following as QPP-accepted Advanced APMs:

- Comprehensive ESRD Care (CEC) – Two-Sided Risk
- Comprehensive Primary Care Plus (CPC+)
- Next Generation ACO Model
- Shared Savings Program – Track 2
- Shared Savings Program – Track 3
- Oncology Model Care (OCM) – Two-Sided Risk
- Comprehensive Care for Joint Replacement (CJR) Payment Model (Track 1 – CEHRT)

CMS estimates the 2017 transition year will have 70,000 to 120,000 clinicians that will be eligible under an Advanced APM; these qualifying clinicians are called “Qualifying APM Participants” or “QPs.” To be a QP the clinician must be a part of an APM entity that (i) receives at least 25 percent of Medicare payments through an Advanced APM, or (ii) services at least 20 percent of its Medicare patients through an Advanced APM.¹¹ After 2018, these thresholds will increase.

If the clinician is deemed to be a QP, the clinician will be excluded from MIPS and receive a five percent incentive payment (*i.e.*, lump sum) in 2019. Currently, the five percent incentive payment is scheduled to continue each year.

Should a provider leave an Advanced APM during 2017, the clinician should either ensure she has seen enough patients or received enough payments through an Advanced APM to qualify for the five percent incentive payment. If neither threshold is met, the clinician may need to submit MIPS performance data to avoid a downward payment adjustment.

Conclusion

CMS has stated that the QPP’s early years are for establishing the “groundwork for expansion towards an innovative, outcome-focused, patient-centered, resource-effective health system.”¹² CMS has intentionally designed a staged approach to the QPP implementation to encourage clinician participation and ensure understanding of the new reimbursement program. CMS acknowledges that changing technology, infrastructure, physician support systems, and clinical practices will cause the QPP to evolve over the next several years to meet their national goals. In anticipation of the end goal, clinicians are strongly encouraged to become familiar with the QPP, understand their reporting requirements and / or eligibility thresholds for each calendar year as they become available, and, if applicable, begin the 2017 data collection process as soon as possible to avoid negative payment adjustments and less than favorable profiles visible to consumers.¹³

(Endnotes)

- 1 See, <https://qpp.cms.gov/>.
- 2 Pub. L. 114-10.
- 3 CMS QPP Executive Summary of Final Rule; available at https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf
- 4 The low-volume threshold is defined as having Medicare allowed billing charges less than or equal to \$30,000 or provides care for 100 or fewer Medicare patients annually. This low-volume threshold will exclude many small or solo practitioners, tabulated to represent 32.5 percent of pre-exclusion Medicare clinicians, but only five percent of Medicare Part B spending. Source: https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf.
- 5 According to CMS, “physician” is defined as a doctor of medicine, doctor of osteopathy (including osteopathic practitioner), doctor of dental surgery, doctor of dental medicine, doctor of podiatric medicine, or doctor of optometry, and, with respect to certain specified treatment, a doctor of chiropractic legally authorized to practice by a State in which he/she performs this function. Source: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MIPS-Scoring-Methodology-slide-deck.pdf>.
- 6 The “cost” category will be calculated in 2017; however, it will not be used to determine the 2019 payment adjustments. The cost category will be used in 2018 to determine payment adjustments going forward. Source: https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf.
- 7 MACRA allows for the potential positive adjustments to be higher or lower than those listed, keeping in mind that MACRA requires budget neutrality. Source: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MIPS-Scoring-Methodology-slide-deck.pdf>.
- 8 CMS will provide further information regarding payment adjustments for 2020 and beyond beginning next year.
- 9 CMS may incentivize clinicians with an additional “exceptional performance” bonus for progressively higher performers that exceed an exceptional PT number of MIPS points. CMS has a pool of \$500 million to fund these additional positive adjustments for performers who exceed the additional PT.
- 10 Reporting as a group requires group reporting across all performance categories.
- 11 Clinicians who do not satisfy these requirements may be able to qualify as Partial QPs under somewhat lower thresholds. Partial QPs do not receive the 5 percent incentive bonus but are entitled to opt out of MIPS.
- 12 CMS QPP Executive Summary of Final Rule; available at https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf.
- 13 For up-to-date information related to the QPP, please visit <https://qpp.cms.gov/>.

Looking To Support A Good Cause?

Pro Bono Partnership of Atlanta (www.pbpatl.org) provides pro bono opportunities specifically geared toward transactional lawyers, including healthcare attorneys. Attorneys provide advice in their area of expertise to 501(c)(3) charities that serve low-income or disadvantaged individuals and cannot afford legal services. Typical healthcare projects include advice on HIPAA and confidentiality, review of informed consent and other documents, and general advice concerning compliance with healthcare regulations. Other projects include contracts, corporate governance, employment, real estate and tax. A current list of volunteer opportunities is available at <http://www.pbpatl.org/for-attorneys/volunteer-opportunities/>. If you are interested in volunteering for one of these matters or want to receive the monthly email with volunteer opportunities, please email Rachel Spears at Rachel.spears@pbpatl.org.



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The Future of Health Care Industry Consolidation: Is the “Arms Race” Between Providers and Insurers coming to a Halt?

by Laurice Rutledge Lambert and Katy Appleby

The historic passage of the Affordable Care Act (ACA) on March 23, 2010, set off a frenzy of mergers and acquisition in the health care industry across the country. This trend peaked in 2015, with almost 1,500 transactions across the health care services and technology sectors.¹ On the other side of the health care industry, 2015 also marked the year of the “mega insurance mergers,” with proposed combinations among the top five health care insurance market players – United Healthcare, Anthem, Aetna, Cigna, and Humana. Specifically, on July 2, 2015 Aetna agreed to buy Humana for \$37 billion (the Aetna/Humana Merger)², and only three weeks later, Anthem and Cigna inked a deal that would have resulted in Anthem acquiring Cigna for around \$54 billion³ (the Anthem/Cigna Merger and together with the Aetna/Humana Merger, the Mergers).

Shortly after the announcements of these combinations, the Mergers were scrutinized by the United States Department of Justice (DOJ). On July 21, 2016, the DOJ, in combination with attorneys general from numerous states and the District of Columbia, sued to block both the Mergers “alleging that the transactions would increase concentration and harm competition across the country.”⁴ The complaint launched against the Aetna/Humana Merger stated that the combination would “substantially lessen competition for the sale of Medicare Advantage plans”⁵ and “substantially lessen competition for the sale of health insurance to individuals on the public exchanges.”⁶ The suit against the Anthem/Cigna Merger alleged that combination would reduce competition in the employer/large group market in 35 metropolitan areas, reduce competition on ACA public exchanges in St. Louis and Denver, and eliminate Cigna, “which has been a leader in the industry’s transition to value-based care.”⁷

The Mergers were also staunchly opposed by health care industry trade groups such as the American Hospital Association (AHA) and the American Medical Association (AMA). In a letter to the DOJ dated Aug. 5, 2015, the AHA stated that “there is the very real potential for [the Mergers] to substantially reduce competition and substantially diminish the insurers’ willingness to be innovative partners with providers and consumers in transforming care.”⁸ On the physician side of the industry, the AMA sprang into action almost immediately after the Mergers were announced and did not stop until they were ultimately defeated.⁹ In connection with its efforts,

in September of 2015, the AMA released the 14th edition of its report, *Competition in Health Insurance: A Comprehensive Study of U.S. Markets*, which set forth a comprehensive analysis of “competition in health insurance markets for 388 metropolitan areas, as well as the 50 states and the District of Columbia.”¹⁰ Locally, the Medical Association of Georgia (MAG) urged Georgians to send comments to Georgia’s Division of Insurance in opposition of the Mergers, and stated that if the Mergers were successful, that “the combined entities [would] control nearly 90 percent of the individual health insurance market in Georgia; [resulting in] a few insurers [having the ability] to institute policies that [would] exacerbate the physician shortage and undermine the economic viability of Georgia’s health care system – especially in rural areas where hospitals and medical practices are struggling to keep their doors open.”¹¹

Perhaps as a result of the strong opposition, or more likely so, because the Mergers threatened long-standing federal antitrust policy, on Jan. 23, 2017, and Feb. 8, 2017, the U.S. District Court for the District of Columbia (the Court) ruled in favor of the DOJ and blocked the Aetna/Humana Merger and the Anthem/Cigna Merger, respectively. The Court’s decision in the Aetna/Humana Merger was based primarily on the fact that the merger would have substantially decreased competition in the Medicare Advantage market in 364 counties.¹² While the decision in the Aetna/Humana Merger focused on the potential decrease in competition in the Medicare Advantage market, the Court’s decision in the Anthem/Cigna Merger cited different grounds, explaining that the merger was “likely to result in higher prices” and have other negative consequences due to the fact that “[i]t w[ould] eliminate the two firms’ vigorous competition against each other for national accounts, reduce the number of national carriers available to respond to solicitations in the future, and diminish the prospects for innovation in the market.”¹³

So what prompted Anthem, Aetna, Cigna, and Humana, the nation’s second, third, fourth and fifth largest insurers, respectively, all of which are quite profitable,¹⁴ to spend the money, time, and incur the risk of significant break-up fees, to attempt the Mergers?¹⁵ One hypothesis is that the uptick in provider-side consolidation that the industry has seen since the passage of the ACA has given providers increased bargaining power over insurers in certain markets, thereby prompting insurance-side consolidation in response.

And perhaps in defense of insurer consolidation, some have compared the Mergers to consolidation in the hospital sector.¹⁶ However, comparing the provider consolidation across the country (that ignited in response to the sweeping changes set into motion by the ACA) to the “mega insurance mergers” is like comparing apples to oranges. Had these Mergers been permitted to move forward, the insurance marketplace would have been consolidated from five (5) giants to three (3) behemoths, “with effectively no possibility that existing firms could replicate their size and scope.”¹⁷ Further, it appears that the ultimate purpose of the Mergers was to increase revenues and profits through acquisition rather than competition, and that the combined insurers would not be able to demonstrate significant or measurable efficiencies and cost-savings to patients or providers.¹⁸ This is in stark contrast to the transactions in the provider sector, which are a direct result of decreasing reimbursement rates, and a move away from fee for service reimbursement towards pay for performance arrangements that favor health systems that offer a full continuum of care and clinically integrated delivery system.¹⁹

So what does this all mean for the future of consolidation on both the provider and insurance side of the health care industry? Although it is too soon to tell, it seems as though the Court’s opinions ruling against the Mergers, may chill consolidation on all sides of the health care industry. In recent years, regulators have challenged numerous large provider mergers on the grounds that the reimbursement rate increase to the combined provider resulting from increased bargaining power against insurers would be passed along to consumers by the insurer via premium hikes.²⁰ In the Court’s rulings on the Mergers (each an Opinion and collectively, the Opinions), the Court found that the opposite would *not* likely hold true -- that the efficiencies created from insurer consolidation would likely not be passed on to consumers.²¹

In the Aetna/Humana Opinion, the Court pointed to testimony from “Aetna’s and Humana’s economist [which] indicate[d] that . . . only about 50 percent of reductions in marginal costs [are] passed through to consumers.”²² In the Anthem/Cigna Opinion, the Court explained that “the antitrust laws are designed to protect competition, and the claimed efficiencies do not arise out of, or facilitate, competition . . . [and] that Anthem’s own documents reveal that the firm has considered a number of ways to capture the network savings for itself and not pass them through to the customers. . . .”²³

Although there are valid reasons for merger and acquisition activity on both sides of the table, it seems as though consolidation in the health care industry may have reached a tipping point. Given that the consumer is the ultimate beneficiary of federal antitrust laws and protections, future merging parties will likely need to be able to prove how the consumer will benefit from a proposed combination, which, in light of the Opinions, may be increasingly difficult to demonstrate on both the provider and insurer sides of the industry.

(Endnotes)

- 1 According to the Irving Levin Associates “health care services” includes all sources of health care provides including hospitals, laboratories and rehabilitation while “health care technology” encompasses biotechnology, eHealth, medical devices, and pharmaceuticals. *See*, Irving Levin Associates, Health Care M&A Deal Volume and Value Exploded in 2015, (Jan 27, 2016), <http://www.levinassociates.com/pr2016/pr1601mam15>.
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- 10 *Id.*
- 11 Kimberly Ramseur, *Why the Aetna/Humana & Anthem/Cigna mergers are bad for Georgia*, Medical Association of Georgia (2017), <http://www.mag.org/advocacy/insurance-merger>.
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- 13 United States of America *et al.*, v. Anthem Inc. *et al.*, No. 16-1493. Slip op. at 3 (D.C. Cir. Feb 8, 2017).
- 14 In 2015, (1) Anthem, which provides health insurance to 39 million people, reported over \$79 billion in revenues, (2) Cigna, which insures 15 million people, reported \$38 billion in revenues, (3) Aetna, which insures 23 million people, reported revenues of \$60 billion, and (4) Humana, which insures 14 million people, reported \$54 billion in revenues. *See* Department of Justice Press Release, *supra* note 5.
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- 23 *Id.*

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New Developments in EMTALA May Impact Liability for Off-Campus Providers

by Kathy Poppitt¹ and Caitlin Pardue²

Although the Emergency Treatment and Active Labor Act (EMTALA) has been in existence for over thirty years, there continues to be confusion around when a hospital becomes subject to EMTALA and what specific obligations arise once EMTALA is implicated. Further compounding this uncertainty has been a recent increase in hospital-based off-campus emergency departments and urgent care centers. Determining whether these types of facilities are subject to EMTALA is often fact dependent, and may require thoughtful analysis of multiple factors.³

Additionally, in December 2016, the Office of Inspector General (OIG) issued a final rule clarifying the Civil Monetary Penalty (CMP) liability guidelines for, among other things, EMTALA violations. (CMP Rule). The CMP Rule, which became effective January 6, 2017, broadens the basis for EMTALA liability.⁴ The increased prevalence of hospital off-campus facilities, coupled with the broader liability under EMTALA, heightens the need for healthcare entities and lawyers who counsel these entities to be mindful of EMTALA compliance.

This article describes general EMTALA obligations for entities subject to the act, discusses when an entity will and will not incur EMTALA obligations, and analyzes the implications of the CMP Rule.

Although this article does not focus on state laws, lawyers and healthcare entities should be cognizant of EMTALA-related laws specific to the state where the entity lies. State laws may impose additional requirements. For example, Georgia requires hospitals providing emergency care to have written policies and procedures for processing individuals who present for emergency care.⁵ Entities should also be aware of potential additional guidance and commentary on EMTALA provided by individual CMS regions.

The Rise of Free-Standing Emergency Departments and Urgent Care Centers

There has been a recent significant increase in standalone emergency care that provides an alternative to traditional hospital-based emergency departments (ED). There are two main types of free-standing EDs: independent and hospital-based. Hospital-based free-standing EDs share a license and Medicare number with the hospital and are thus subject to EMTALA, and can bill Medicare and Medicaid at the current hospital rate. In comparison, independent free-standing EDs are not able to enroll in Medicare which exempts them from EMTALA but also keeps them from generating revenue from Medicare. Depending on the circumstances, like in Georgia,

a state's Certificate of Need laws may apply and should also be considered.⁶

Both hospital-based and independent EDs have the potential to meet the needs of medically underserved areas, relieve overburdened hospital EDs, and offer shorter wait times as a convenient alternative for patients.⁷ In an effort to address rural hospital shut-downs, Georgia recently allowed rural hospitals to downgrade their services to become "rural free-standing emergency departments."⁸ However, a 2015 report from Georgia's Rural Hospital Stabilization Committee determined that these types of free-standing EDs were not financially viable, due in part to lower provider rates for free-standing EDs.⁹

There has also recently been growth in the number of urgent care centers. Standalone urgent care centers can also be independent or provider-based. Urgent care centers differ from EDs in the types of services they provide. Urgent care centers generally provide less acute care, while EDs have the capabilities to treat critical medical conditions. Generally, neither independent nor hospital-based urgent care centers are subject to EMTALA, since an urgent care center is not an ED. However, hospitals must take care not to operate their hospital-based urgent care centers in a way that meets the EMTALA definition of a Dedicated Emergency Department (DED), discussed below, and thus subject to EMTALA requirements.

What Does EMTALA Require?

EMTALA imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide a medical screening examination (MSE) to all persons requesting examination or treatment. The intention of the MSE is to identify whether an emergency medical condition (EMC) exists, regardless of an individual's ability to pay. If the hospital determines the person has presented with an EMC, the hospital is required to either provide stabilizing treatment, or admit for inpatient care. If a hospital is unable to stabilize the person within its capability, or if the patient requests it, an appropriate transfer to another facility should be implemented.

When is EMTALA Triggered?

Generally, an entity will only become subject to EMTALA if it bills to a federally-funded healthcare program and has a DED.¹⁰ Since it is usually clear whether the entity participates in a federally-funded healthcare program, the thornier issue becomes determining whether the entity has a DED for EMTALA purposes.

Dedicated Emergency Department – Three Part Test

If an entity meets any of the following three definitions of a DED, then it will be subject to EMTALA; this applies regardless of whether the facility is located on or off the main hospital campus. The three definitions are set out in EMTALA at 42 C.F.R. § 489.24(b):

1. The department is licensed by the state in which it is located under applicable law as a dedicated emergency department;
2. The department is held out to the public as a place that provides emergency medical care on an unscheduled basis; or
3. During the previous CY, at least one-third of the department's outpatient visits were for emergency medical conditions.

The first definition is straightforward: if the hospital department is licensed as an emergency department, EMTALA will apply.

However, the second and third definitions can occur even if the department is not licensed as an emergency department. In the second definition, a department will be deemed a DED if it is “held out to the public” as an emergency department. This option is very fact dependent and CMS will consider many factors, which may include:

- The name of the facility;
- The types of signs posted around the facility;
- The kinds of advertising the facility uses; and
- Other fact-specific factors dependent on the unique circumstances of the situation.

Given the variety of fact-dependent circumstances incorporated in the second definition, whether an entity meets this requirement is somewhat subjective. A recent Rhode Island case addressed this precise issue, and may provide helpful guidance when determining whether an entity will be considered a DED. In that case, the Defendant hospital's motion for summary judgment contended that EMTALA did not apply to the facility.¹¹ The court denied the motion, noting that EMTALA applied because the facility held itself out to be an emergency center because the clinic used the word “Urgent” in its name, and because the medical staff knew that some patients came to the clinic for emergency services. The opinion noted that the only place where the clinic discussed that it did not offer emergency services was on its website, which the court found insufficient. The case is currently set for trial. Urgent care centers that are not hospital-based are not subject to EMTALA since they could never meet the definition of a DED.

The third way an entity may be considered to be a DED, and thus subject to EMTALA, is if it provides at least one-third of all its outpatient visits for unscheduled EMCs, as described more fully in the SOM Appendix V. For each case, surveyors are instructed to ask three

questions: whether the individual was an outpatient, whether the individual had an unscheduled appointment, and whether the individual had an EMC and received stabilizing treatment.

All three questions must be answered “yes” to be counted toward the one-third criterion. If at least one-third of the cases reviewed receive a “yes” answer, then the hospital has an EMTALA obligation.

Once EMTALA is Triggered, What is an Entity Required to Do?

If an entity meets any of the three definitions of a DED discussed above, and if an individual “comes to the hospital,” the hospital must provide an appropriate MSE. If the MSE reveals an EMC, the entity must provide stabilizing treatment or an appropriate transfer. Note that if the hospital admits the individual as an inpatient, the hospital's EMTALA obligations end. However, the hospital will still be subject to other conditions of participation and standards of care requirements for that patient.

“Comes to the Hospital”

Different EMTALA obligations may arise depending on where the individual presents with a medical condition: the individual may present directly to the DED, or the individual may present somewhere on the hospital main campus other than the DED.

1. The Individual has Presented Directly to the DED

In the first situation, to present directly to the DED, it does not matter whether the facility is located on the hospital's main campus or is located off-campus. However, not all off-campus facilities will be subject to EMTALA. Specific off-campus issues are discussed below.

If an individual with a medical condition presents directly to the DED and requests examination or treatment for an emergency medical condition, the individual must receive an MSE that is appropriate for that medical condition. Once a person receives an MSE and a determination is made that an EMC does not exist, the hospital's EMTALA obligations end for that person. A hospital is not obligated under EMTALA to provide screening services beyond those necessary to determine that there is no EMC.

Off-Campus Provider-Based Departments vs. Freestanding Emergency Centers

If the DED is located off-campus, then it must be provider-based to implicate EMTALA. Importantly, CMS makes a clear distinction between off-campus provider-based departments (“off-campus PBDs”), that are subject to EMTALA, and independent freestanding emergency centers, that are not. “Provider-based” is a reimbursement issue, which allows a facility to be considered part of the hospital, even if the department is far away from the main campus. In contrast, independent freestanding EDs are typically owned and operated by non-hospital for-profit entities and are not considered PBDs. Both facilities offer similar services. Since independent freestanding

emergency centers are not considered to be PBDs, they are not recognized by CMS or able to participate in Medicare, and are, thus, not bound to comply with EMTALA.

2. The Individual has Presented on the Hospital Campus Other Than the DED

In the second situation, if an individual presents with an emergent condition at any department on the hospital's campus, then EMTALA will be triggered. "Campus" is defined under EMTALA as all physical areas within 250 yards adjacent to any of the hospital's main buildings. For example, this means that EMTALA will be triggered if an individual with an EMC presents on the sidewalk immediately outside the radiology department a half a mile away from the DED, so long as the radiology department and DED are located on the main campus of the hospital. The main exception to this rule are medical offices or similar buildings on the main campus that are not actually part of the hospital.

Stabilizing Treatment

If an MSE establishes that an individual has presented with an EMC, the ED staff must provide stabilizing treatment or an appropriate transfer. Stabilizing treatment is defined as "such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that . . . the woman has delivered the child and the placenta."¹² If a patient is not stabilized, the facility may not transfer or discharge unless the patient requests a transfer or a physician certifies that the benefits of transfer outweigh the risks.

Specific Transfer Issues for Off-Campus PBD Emergency Departments

Because EMTALA treats the off-campus PBD emergency department as part of the hospital entity, moving an individual from the off-campus ED to the hospital's main campus is not considered a transfer.¹³ Therefore, for an individual who presents to an off-campus ED with an EMC, hospitals do not need to meet the EMTALA transfer requirements to move the patient to the hospital's main campus for stabilizing or inpatient treatment that cannot be provided at the off-campus site.¹⁴

An off-campus ED may transfer to a nonaffiliated hospital when: (1) the individual cannot be stabilized at the off-campus ED, (2) the receiving facility has available space and can provide the necessary services, and (3) the benefits of the transfer outweigh the risks. There is no requirement under EMTALA that the individual be transferred to the main campus hospital, especially if neither the off-campus emergency department nor the affiliated hospital can provide the necessary services. These types of transfer issues are likely to crop up at off-campus EDs that are closer to another hospital than to its own main campus, whether because the transferring physician believes the shorter transfer is necessary or the patient requests a transfer to the nonaffiliated hospital. That being said, EMTALA violations are often cited when the transferring

hospital is shown to provide the same services for which it is transferring the patient and/or has physicians on-call with privileges to provide those services. In situations where the patient requests transfer to a hospital not affiliated with the off-campus ED, the request and reasons for it should be well documented.

EMTALA Penalties

Violating EMTALA can result in heavy penalties. Medicare-participating hospitals and responsible physicians may be liable for CMPs of up to \$50,000 (\$25,000 for hospitals with fewer than 100 State-licensed and Medicare-certified beds) for each negligent violation of their respective EMTALA obligations.¹⁵ Additionally, though not often used, providers face potential exclusion from Medicare and Medicaid for EMTALA violations, a potentially devastating action.¹⁶

When determining the amount of any EMTALA-related CMP, the government will consider the following circumstances as either mitigating or aggravating factors:

- Degree of culpability;
- Seriousness of the affected individual's condition;
- Prior offenses;
- Financial condition;
- Nature and circumstances of the incident; and
- Other matters, including taking immediate appropriate action against responsible physicians, developed and implemented corrective action plans, and patient harm (or lack thereof).¹⁷

Recent Broadening of EMTALA Liability

The OIG CMP Rule became effective on Jan. 6, 2017, and clarifies EMTALA liability guidelines for CMPs.¹⁸ Specifically, the CMP Rule affirms that the statutory language imposes a negligence standard for EMTALA culpability, and thus does not require the OIG to show willful conduct by the provider. It also revises the definition of "responsible physician," clarifying that on-call physicians at hospitals with specialized capabilities are considered "responsible physicians" and have the attendant responsibilities of that designation.¹⁹

In addition to these clarifications, the CMP Rule also amends the mitigating and aggravating factors the government will use to determine a hospital or physician's liability under EMTALA:

- **Removes "intent to leave" as a mitigating factor.** Through its enforcement activities, OIG found that the fact a person may have "demonstrated a clear intent to leave" was not a proper mitigating factor on the hospital's liability. OIG reasoned that the clear intent to leave may have been based on the hospital's failure to properly screen the individual, which should not lessen the hospital's liability.
- **Adds "corrective action" as a mitigating factor.** Situations in which a hospital takes appropriate and

timely corrective action in response to a violation will be considered a mitigating factor. However, the corrective action must be completed prior to CMS initiating an investigation.

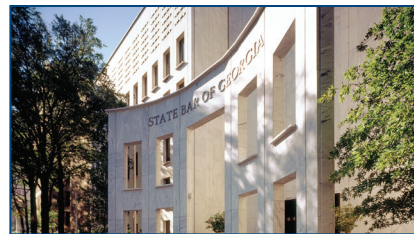
- **Adds “risk of patient harm” as an aggravating factor.** The previous regulation required OIG to prove actual patient harm. Noting that “this formulation is overly constrained,” the new CMP Rule adds risk of patient harm, which includes premature discharge or the need for additional services.

Given the potential impact an EMTALA violation can have on a healthcare entity, it would be prudent for hospitals with an off-campus PBD emergency department or urgent care center to review its EMTALA procedures and re-educate staff as needed. Documentation is critical for EMTALA purposes; without proper documentation, the government will presume proper examinations, stabilizing or transfers either never happened or were not done properly. Proactive efforts to comply with EMTALA can ensure a hospital can significantly reduce the risk of incurring EMTALA liability and penalties in the future.

(Endnotes)

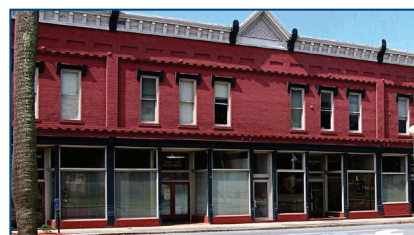
- 1 Kathy Poppitt is a partner in King & Spalding’s Healthcare Practice in Austin, Texas.
- 2 Caitlin Pardue is an associate in the Atlanta office of King & Spalding and a member of the Healthcare Practice Group.
- 3 The EMTALA statute is found at 42 U.S.C. § 1395, while the main regulations are found at 42 C.F.R. §§ 489.20 & 489.24. These regulations are part of the Medicare provider agreement and thus obligate all entities who participate in Medicare to abide by EMTALA requirements. EMTALA penalties are found at 42 C.F.R. §§ 1003.103 & 1003.106. CMS’ EMTALA Interpretive Guidelines, found at Appendix V of the State Operations Manual, provide helpful insight into how CMS interprets EMTALA.
- 4 81 *Fed. Reg.* 88334 (Dec. 7, 2016).
- 5 See Ga Comp. R. & Regs. 111-8-40-.31.
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- 7 Catherine Gutierrez et al., *State Regulation of Freestanding Emergency Departments Varies Widely, Affecting Location, Growth, and Services Provided*, 35 *Health Affairs* 1857 (2016), http://scholar.harvard.edu/files/cutler/files/health_aff-2016-gutierrez-1857-66.pdf.
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- 10 Generally, receiving hospitals are only obligated to accept transfers under EMTALA if the receiving hospital has the capability and capacity to treat the individual.
- 11 See *Friedrich v. South County Hospital Healthcare System*, No. 14-353S (D. R.I. 2016).
- 12 42 C.F.R. § 489.24(b).
- 13 See SOP, Appendix V, § 489.24(e).
- 14 *Id.*
- 15 See 42 C.F.R. §§ 1003.106(d) & 489.53(a)(10).
- 16 *Id.*
- 17 42 C.F.R. §§ 1003.106(d).
- 18 See 81 *Fed. Reg.* 88334 (Dec. 7, 2016).
- 19 *Id.*

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OIG 2017 Work Plan—The New and the Familiar

by Tara Ravi

On Nov. 10, 2016, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released the FY 2017 Work Plan (Work Plan) outlining its priorities for new and ongoing audits and evaluations for fiscal year 2017.¹ The Work Plan also provides an update on items that have been completed, postponed, or canceled, and identifies new items that have begun or have been planned since April 2016.² Similar to previous versions, the Work Plan continues its focus in areas identified as particularly vulnerable to fraud and abuse, including nursing homes, home health, hospice, and durable medical equipment.³ This year, the Work Plan also highlights new areas of risk, including hyperbaric oxygen therapy services, drug compounding, physician payments identified in the Open Payments Program, and compliance with accountable care models.⁴

The Work Plan has indicated its intention to pursue these priorities through audits, investigations, inspections, industry guidance (including advisory opinions), and enforcement actions (including actions to impose civil monetary penalties, assessments and administrative sanctions, such as exclusions).⁵ Experience demonstrates that those issues identified in the Work Plan are likely to be subject to additional government scrutiny in coming year. As such, healthcare providers and organizations would be well advised to use the Work Plan to identify corporate compliance risks relevant to their particular line of business, to prioritize audit focus areas within their audit work plan, and to facilitate the development and implementation of compliance program activities.

Notable Work Plan items for FY 2017 include:

New Hospital Initiatives

Hyperbaric oxygen therapy services — provider reimbursement in compliance with federal regulations

The Work Plan indicated its intention to determine whether Medicare payments related to hyperbaric oxygen (“HBO”) outpatient claims were reimbursed in accordance with federal requirements.⁶ Prior Work Plan audits raised concerns that (i) beneficiaries had been treated for noncovered conditions,⁷ (ii) the medical documentation did not adequately support HBO treatments reimbursed by a federal health care program, and (iii) beneficiaries received medically unnecessary HBO treatments.⁸

Incorrect medical assistance days claimed by hospitals

Medicare-participating hospitals that serve a disproportionate share of low-income patients may receive disproportionate share hospital payments, which payments are determined using a complicated calculation

consisting of mainly of the number of Medicaid patient days that the hospitals furnish are report on their cost report. Because these calculations are particularly complicated, the Work Plan has determined that Medicare disproportionate share hospital payments are at risk of overpayment. The Work Plan intends to evaluate whether, with respect to Medicaid patient days, Medicare administrative contractors properly settled Medicare cost reports in accordance with federal requirements.⁹

Inpatient psychiatric facility outlier payments

Inpatient psychiatric facilities, either freestanding hospitals or specialized hospital-based units, provide active psychiatric treatment to meet the urgent needs of those experiencing an acute mental health crisis, which may involve mental illnesses or alcohol- or drug-related problems. Due to a nineteen percent (19 percent) increase in total Medicare payments for stays that resulted in outlier payments from FY 2014 to FY 2015, the Work Plan indicated its intention to determine whether duly qualified inpatient psychiatric facilities nationwide complied with Medicare documentation, coverage, and coding requirements for stays that resulted in outlier payments.¹⁰

Case review of inpatient rehabilitation hospital patients not suited for intensive therapy

The Work Plan indicates in the Work Plan that it intends to conduct a study to assess a sample of rehabilitation hospital admissions to determine whether the patients participated in and benefited from intensive therapy.¹¹ For patients who were not suitable candidates, the Work Plan intends to identify the reasons they were not able to participate and benefit from therapy.¹²

New Skilled Nursing Facility and Nursing Home Initiatives

Nursing home complaint investigation data brief

A 2006 Work Plan report¹³ found that state agencies did not investigate some of the most serious nursing home complaints (*i.e.*, complaints qualifying as “immediate jeopardy”¹⁴ or “actual harm”¹⁵) within the required timeframe (two and ten days from the date of receipt of the complaint, respectively).¹⁶ Citing to this finding, the Work Plan indicated in the Work Plan its goal of determining if and to what extent state agencies investigate the most serious nursing home complaints within the required timeframes.¹⁷

Skilled nursing facilities — unreported incidents of potential abuse and neglect

The Work Plan plans to assess the incidence of abuse and neglect of Medicare beneficiaries receiving treatment in skilled nursing facilities and determine whether these

incidents were properly reported and investigated in accordance with applicable federal and state requirements.¹⁸ The OIG also plans to interview state officials to determine if each sampled incident was reported, if required, and whether each reportable incident was investigated and subsequently prosecuted by the state, if appropriate.¹⁹

Skilled nursing facility reimbursement

Based on previous OIG findings indicating that skilled nursing facilities are billing for higher levels of therapy than were provided or were reasonable or necessary,²⁰ the OIG intends to review the documentation at selected skilled nursing facilities to determine if their documentation meets the requirement for each particular resource utilization group.²¹

Skilled nursing facility adverse event screening tool

This OIG initiative will describe the purpose, use, and benefit of a skilled nursing facility adverse event trigger tool²² with the goal of disseminating practical information about the tool for use by those involved with the skilled nursing industry.²³

New Hospice and Home Health Initiatives

Medicare hospice benefit vulnerabilities and recommendations for improvement

The OIG plans to summarize its evaluations, audits, and investigative work with respect to Medicare hospices and highlight key recommendations for protecting beneficiaries and improving the program.²⁴

Review of hospices' compliance with Medicare requirements

The OIG indicated in the Work Plan its plan to review hospice medical records and billing documentation to determine whether Medicare payments for hospice services were made in accordance with Medicare requirements.²⁵

Hospice home care — frequency of nurse on-site visits to assess quality of care and services

Further, the OIG indicates its plan to determine whether registered nurses made required on-site visits to the homes of Medicare beneficiaries who were in hospice care, as required under 42 C.F.R. § 418.76(h)(1)(i).²⁶

Comparing home health agency survey documents to Medicare claims data

The OIG will determine whether home health agency surveys are accurately providing patient information to state agencies for recertification surveys.²⁷

New Initiatives for Medical Equipment and Supplies

Part B services during non-Part A nursing home stays: Durable medical equipment

The OIG will conduct a study to determine the extent of inappropriate Medicare Part B payments for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) provided to nursing home residents during non-Part A stays in 2015. The OIG will

also determine whether CMS has a system in place to identify inappropriate payments for DMEPOS and recoup payments from suppliers.²⁸

Medicare market share of mail-order diabetic testing strips: April 1 through June 30, — mandatory review

As required under the competitive bidding program, pursuant to section 1847(b)(10)(B) of the Social Security Act, the OIG will review and report the market share of diabetic testing strips to help CMS determine how the National Mail Order Reconnect may impact shifts in the market.²⁹

Positive airway pressure ("PAP") device supplies — supplier compliance with documentation requirements for frequency and medical necessity

The OIG will review claims for frequently replaced PAP device supplies to determine whether documentation requirements for medical necessity, frequency of replacement and other Medicare requirements are met.³⁰

Other Provider and Supplier Initiatives

Monitoring Medicare payments for clinical diagnostic laboratory tests — mandatory review

In addition to the specific provider and supplier initiatives addressed above, the OIG intends to analyze Medicare payments for clinical diagnostic laboratory tests performed in 2016 and monitor CMS' implementation of the new Medicare payment system for these tests.³¹

Medicare payments for transitional care management

The OIG also plans to evaluate whether payments for transitional care management services were made in accordance with Medicare requirements.³² Specifically, the transitional care management services billing requirements prohibit a provider from billing transitional care management services during the same services period as certain other Medicare-covered services such as chronic care management, end-stage renal disease, and prolonged services, without direct patient contact.³³

Medicare payments for chronic care management

Similarly, the OIG plans to evaluate whether payments for chronic care management services were in accordance with Medicare billing requirements³⁴

Data brief on financial interests under the Open Payments Program

Analyzing data extracted from the Open Payments Program website, the OIG plans to determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations for the purpose of determining the number and nature of financial relationships (and assumedly whether these relationships result in overutilization in the Medicare program).³⁵ The OIG will also evaluate the volume and total dollar amount associated with drugs and DMEPOS ordered by physicians with related financial relationships in Medicare Parts B and D for 2015.³⁶

Power mobility devices equipment

Continuing its longstanding focus on power mobility devices, the OIG has committed to compiling the results of prior OIG audits, evaluations, and investigations with respect to claims for power mobility device equipment paid by Medicare with the goal of identifying trends in payment, compliance, and fraud vulnerabilities and offer recommendations to improve detected vulnerabilities.³⁷

New Prescription Drugs Initiatives

Drug waste of single-use vial drugs

The OIG plans to determine the amount of waste for the 20 single-use-vial drugs with the highest amount paid for waste as identified by the JW modifier³⁸ and provide specific examples of single-use-vial drugs where a different size vial could significantly reduce waste.³⁹

Potential savings from inflation-based rebates in Medicare Part B

The OIG will examine the amount the federal government could potentially collect from pharmaceutical manufacturers if inflation-indexed rebates were required under Medicare Part B, similar to those statutorily mandated rebates that enable Medicaid to recoup from pharmaceutical manufacturers.⁴⁰

Medicare Part D rebates related to drugs dispensed by 340B pharmacies

Drug manufacturer rebates reduce the cost of the Part D program to beneficiaries and the federal government. Manufacturers, however, frequently do not pay rebates for Part D prescriptions filled at 340B covered entities and contract pharmacies since they are already providing a discount on the purchase of the drug. The OIG plans to determine the upper bound of what could be saved if pharmaceutical manufacturers paid rebates for drugs dispensed through Medicare Part D program at 340B Drug Pricing Program covered entities and contract pharmacies.⁴¹

Questionable billing for compounded topical drugs in Part D

Citing to a substantial increase in Part D spending for compounded topical drugs between 2006 and 2015, the OIG plans to perform a review that will describe appropriate billing practices for topical compounded drugs under Part D and identify pharmacies with questionable Part D billing for such drugs and any associated prescribers.⁴²

Medicare Part D payments for service dates after individuals' dates of death

The OIG plans to evaluate whether prospective payments were made to Part D sponsors, *i.e.*, private prescription drug plans and Medicare Advantage plans, after beneficiaries' date of death resulting in an overpayment. Part D sponsors are required to disenroll a beneficiary from its prescription drug plan on the death of the individual, which is effective the first day of the calendar month following the month of death.⁴³

Billing and Payment Initiatives

Medicare payments for service dates after individuals' dates of death

The OIG also plans to review CMS' policies and procedures that ensure that payments are not made for Medicare services ostensibly rendered to deceased individuals.⁴⁴

Management review — CMS's implementation of the Quality Payment Program

The OIG intends to perform a review that will describe the timelines and key milestones CMS has established for implementing the Quality Payment Program provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)⁴⁵ and identify the key challenges and potential vulnerabilities CMS faces throughout implementation.⁴⁶

New Medicaid Initiatives

States' managed care organization (MCO) Medicaid drug claims

Pursuant to the drug rebate program, a drug manufacturer must have a rebate agreement with CMS to have its outpatient drugs covered under Medicaid.⁴⁷ Citing to this requirement, the OIG indicated in the Work Plan its intent to determine whether MCO capitation payments included reimbursement for drugs that are not covered under the Medicaid program.⁴⁸

Data brief on fraud in Medicaid personal care services

The OIG also plans to issue a data brief providing an overview of personal care services statistical data collected since 2012, including state and federal investigations, indictments, convictions, and recoveries involving fraud and patient abuse or neglect with respect to Medicaid personal care services.⁴⁹

Delivery System Reform Incentive Program

The OIG review plans to ensure that states selected to participate in the program, *i.e.*, California, Kansas, Massachusetts, New Hampshire, New Jersey, New Mexico, New York, Texas, Virginia, and Washington, adhered to applicable federal and state requirements when they made delivery system reform incentive payments to providers.⁵⁰

Accountable care in Medicaid

The OIG intends to review selected accountable care models in Medicaid for compliance with relevant state and federal requirements applicable to such accountable care model, *e.g.*, medical homes and accountable care organizations.⁵¹

Third-party liability payment collections in Medicaid

The OIG also intends to determine whether all states have taken action to ensure that Medicaid is the payer of last resort by identifying whether a third-party payer exists and if the state correctly reports the third-party liability to CMS.⁵²

Medicaid overpayments reporting and collections

For OIG audits in which CMS concurred with recommendations to collect Medicaid overpayments from a state, the OIG plans to determine whether the overpayments have been recouped and properly reported to CMS.⁵³

Overview of states' risk assessments for Medicaid-only provider types

The OIG intends to review states' assignment of Medicaid-only providers to the federally designated risk categories of high, moderate, and limited as well as any challenges states face in screening Medicaid-only provider types.⁵⁴

Health-care related taxes: Medicaid MCO compliance with hold-harmless requirement

The OIG plans to evaluate whether health-care-related tax programs for MCOs meet federal hold-harmless requirements in 42 C.F.R. § Sec. 433.68 by examining the tax programs in large states that tax MCOs.⁵⁵

Health-care-acquired conditions — Medicaid MCOs

The Patient Protection and Affordable Care Act (ACA), section 2702, and implementing regulations at 42 C.F.R. § 447.26, prohibit federal payments for provider preventable conditions. Because the OIG has previously identified problems with states making fee-for-service payments associated with provider preventable conditions,⁵⁶ the OIG has decided to expand the scope of review to include managed care arrangements. Thus, the OIG intends to review whether Medicaid MCOs have continued to make payments to providers for inpatient hospital services related to the treatment of certain provider preventable conditions.⁵⁷

Conclusion

The addition of an initiative to the Work Plan generally reflects government concern that fraud and/or compliance violations exist in the specified area. While it is too early to tell what impact the Trump administration will have on the OIG's enforcement activities, federal law nevertheless requires the prompt return of overpayments and creates the risk of potential False Claims Act liability, exclusion, and civil monetary penalties. Providers and suppliers should examine the entire OIG Work Plan as it applies to their business and dust off their existing risk assessment and compliance plan to ensure the risk areas identified in the Work Plan are adequately accounted for.

(Endnotes)

- 1 See OIG Work Plan - 2017, U.S. Department of Health and Human Services, Office of Inspector General, *available at* <https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/HHSpercent20OIGpercent20Workpercent20Planpercent202017.pdf> ("2017 Work Plan").
- 2 *Id.* at v.
- 3 Compare OIG Work Plan - 2016, U.S. Department of Health and Human Services, Office of Inspector General, *available at* <https://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf> and OIG Work Plan - 2015, U.S. Department of Health and Human Services, Office of Inspector General, *available at* <https://oig.hhs.gov/reports-and-publications/archives/>

- workplan/2015/FY15-Work-Plan.pdf, with 2017 Work Plan at 1-52.
- 4 See 2017 Work Plan at 2, 16-17, 40 and 61.
- 5 See *id.* at 52-57.
- 6 See *id.* at 2.
- 7 See, e.g., Hyperbaric Oxygen Therapy Its Use and Appropriateness, OIG, Oct. 2000 (OEI 06-99-00090) *available at* <https://oig.hhs.gov/oei/reports/oei-06-99-00090.pdf>.
- 8 See 2017 Work Plan at 2.
- 9 See *id.*
- 10 See *id.*
- 11 See *id.* at 3.
- 12 See Case Review of Inpatient Rehabilitation Hospital Patients Not Suited for Intensive Therapy, U.S. Department of Health and Human Services, Dec. 2016 (OEI-06-16-00360) *available at* <https://oig.hhs.gov/oei/reports/oei-06-16-00360.pdf>.
- 13 See Nursing Home Complaint Investigations, OIG, Jul. 2006 (OEI-01-04-00340) *available at* <https://oig.hhs.gov/oei/reports/oei-01-04-00340.pdf>.
- 14 The Center for Medicare and Medicaid Services ("CMS") State Operations Manual ("SOM") defines "immediate jeopardy," the most serious allegation category, as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." See CMS State Operations Manual, Ch. 5, Complaint Procedures, Sec. 5030A (Rev. 155, 06-10-16). See also 42 C.F.R. § 489.3.
- 15 The SOM Chapter 5, addressing Complaint Procedures, defines "actual harm," which is the second most serious allegation category, as "a provider's alleged noncompliance with one or more requirements or conditions may have caused harm that negatively impacts the individual's mental, physical, and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the State agency is indicated." See *id.* at Sec. 5030B.
- 16 2017 Work Plan at 8.
- 17 See *id.*
- 18 See *id.*
- 19 See *id.*
- 20 *C.f.*, The Medicare Payment System for Skilled Nursing Facilities Needs to be Reevaluated, U.S. Department of Health and Human Services, Office of Inspector General, Sept. 2015 (OEI-02-13-00610) *available at* <https://oig.hhs.gov/oei/reports/oei-02-13-00610.pdf>. See also Questionable Billing for Skilled Nursing Services, U.S. Department of Health and Human Services, Office of Inspector General, Dec. 2010 (OEI-02-09-00202) *available at* <https://oig.hhs.gov/oei/reports/oei-02-09-00202.pdf>.
- 21 2017 Work Plan at 9.
- 22 See Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries, U.S. Department of Health and Human Services, Office of Inspector General, Feb. 2014 (OEI-06-11-00370) *available at* <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf> (describing application of SNF Trigger Tool).
- 23 2017 Work Plan at 9.
- 24 See *id.* at 10.
- 25 See *id.* at 11 (citing to Medicare conditions of and limitations on payment for hospice services at 42 C.F.R. Part 418, Subpart G).
- 26 *Id.* (citing requirement at 42 C.F.R. § 418.76(h)(1)(i) that a registered nurse make an on-site visit to the patient's home at least once every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs).
- 27 See *id.*
- 28 See *id.* at 12.
- 29 See *id.*
- 30 See *id.* at 13.
- 31 See *id.* at 15.
- 32 See *id.* at 16.
- 33 See FY 2013 Medicare Physician Fee Schedule ("PFS") Final Rule,

- 77 Fed. Reg. 68979-68993 (Nov. 16, 2012); *see also* Transitional Care Management Services, CMS Medicare Learning Network, Dec. 2016 (ICN 908628) *available at* <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Transitional-Care-Management-Services-Text-Only.pdf>.
- 34 2017 Work Plan at 16. *See also* 2014 PFS Final Rule, 78 Fed. Reg. 74414-74427 (Dec. 10, 2013); 2015 PFS Final Rule, 79 Fed. Reg. 67715-67730 (Nov. 13, 2014); Chronic Care Management Services Changes for 2017, CMS Medicare Learning Network, Dec. 2016 (ICN 909433) *available at* <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Chronic-Care-Management-Services-Changes-2017-Text-Only.pdf>.
- 35 The Open Payments Program is a federal program, required under Section 6002 of the ACA, that collects information about the payments drug and device companies make to physicians and teaching hospitals for things like travel, research, gifts, speaking fees, and meals. The program also collects information about ownership interests physicians or their immediate family members have in these types of companies. This data is then made available to the public each year on the CMS Open Payment website located at <https://www.cms.gov/openpayments/>.
- 36 *See* 2017 Work Plan at 16-17.
- 37 *See id.* at 17.
- 38 The modifier “JW” is used to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded. For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95 unit dose is billed on one line, while the discarded 5 units shall be billed on another line by using the JW modifier. Both line items would be processed for payment. *See* Medicare Claims Processing Manual, Pub. 100-04, Ch. 17, Sec. 40 (revised on Jan. 1, 2017).
- 39 *Id.* at 22.
- 40 *See id.*
- 41 *Id.* at 29.
- 42 *Id.* at 29-30.
- 43 *Id.* at 30.
- 44 *Id.* at 26.
- 45 MACRA establishes a new Medicare physician payment system, known as the Quality Payment Program, which ends the Sustainable Growth rate formula. Under the Quality Payment Program, clinicians may receive positive or negative Medicare payment adjustments depending on their performance across a range of measures; alternatively, clinicians can opt to participate in an Advanced Alternative Payment Model, which offers other quality and payment incentives. *See* Overview of the Quality Payment Program, *available at* <https://qpp.cms.gov/>.
- 46 2017 Work Plan at 26-27.
- 47 Section 1927(a)(1) of the Social Security Act.
- 48 2017 Work Plan at 33.
- 49 *See id.* at 36.
- 50 *See id.* at 40.
- 51 *See id.*
- 52 *See id.*
- 53 *See id.* at 41.
- 54 *See id.*
- 55 *See id.*
- 56 *See* Illinois Claimed Some Improper Federal Medicaid Reimbursement for Inpatient Hospital Services Related to Treating Provider-Preventable Conditions, U.S. Department of Health and Human Service, Office Inspector General, Sept. 2016 (A-05-15-00033) *available at* <https://oig.hhs.gov/oas/reports/region5/51500033.pdf>; Idaho Claimed Some Improper Federal Medicaid Reimbursement for Inpatient Hospital Services Related to Treating Provider-Preventable Conditions, U.S. Department of Health and Human Service, Office Inspector General, Sept. 2016 (A-09-15-02013) *available at* <https://oig.hhs.gov/oas/reports/region9/91502013.pdf>; Washington Claimed Some Improper Federal Medicaid Reimbursement for Inpatient Hospital Services Related to Treating Provider-Preventable Conditions, U.S. Department of Health and Human Service, Office Inspector General, Sept. 2016 (A-09-14-02012) *available at* <https://oig.hhs.gov/oas/reports/region9/91402012.pdf>.
- 57 *See id.* at 46.



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