

October 2018

Dear Health Law Section Members:

The Health Law Section (“HLS”) website has been updated with August through September 2018 articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented to HLS members for general information only and do not constitute legal advice from The Florida Bar or its Health Law Section. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

Jocelyn Ezratty, Esq., Di Pietro Partners, LLP

Christian Perez Font, Managing Partner, Thinkeen Legal, P.A.

Anne Kelley, J.D. Candidate, University of Florida

Erica C. Mallon, Esq., Corporate Counsel, Greenway Health

Zachary Merson, Corporate Counsel, Availity

Francesca Ozinal, Associate, Epstein Becker & Green, P.C.

Kathleen Premo, Member, Epstein Becker & Green, P.C.

Megan Robertson, Associate, Epstein Becker & Green, P.C.

Timothy Wombles, Esq., Associate, Nelson Mullins Broad and Cassel

Thank you,

Jamie Gelfman, Esq., Nelson Mullins Broad and Cassel, HLS Editor in Chief

Christian Perez Font, Esq., Thinkeen Legal, P.A., HLS Team Editor

Elizabeth Scarola, Esq., Epstein Becker Green P.A., HLS Team Editor

COMPLIANCE UPDATES

Advisory Opinion Finds Group Purchasing Organization Able to Provide Services to its Affiliate Hospitals and Entities

As health providers turn to more innovative offerings and business models, uncertainties arise with structuring new deals. In its July 30, 2018 Advisory Opinion, No. 18-07,¹ the Office of Inspector General (“OIG”) interpreted new specialty uses for Group Purchasing Organizations (“GPOs”) under the federal Anti-Kickback Statute (the “Advisory Opinion”).

GPOs negotiate volume discounts on behalf of hospitals and health care facilities. They charge product and service vendors an administrative fee in exchange for access to sales at the applicable hospitals and health care facilities.

In the Advisory Opinion, a GPO sought advice (the “Requestor”) regarding a proposed arrangement under which it would offer GPO negotiation services for innovative and specialty healthcare products and services. These specialty products and services are fairly new to the healthcare industry and are not offered by typical GPOs. In the Advisory Opinion, the Requestor certified that it offered a portfolio of specialty products and services, including “information technology platforms, emergency department services and staffing, physician recruitment, telemedicine physician consults, human resources personnel and services, and refurbished equipment.” Much of these specialty group negotiation services are a reflection of the evolving business models that include outsourcing personnel services and incorporating new technology into patient care.

The Requestor sought clarification on the existing corporate structure of its parent company. The Requestor’s parent company also owns hospitals and health care facilities. The Requestor wished to provide group negotiation services to those hospitals and health care facilities owned by the Requestor.

Although the arrangement would not qualify for GPO safe harbor protection² because it would not satisfy the definition of a “GPO” as defined by the regulations, the OIG concluded that such an arrangement would not warrant administrative prosecution.

The OIG emphasized a few points to justify its position. The Requestor’s affiliated hospitals and facilities wished to utilize the specialty products and services provided by its innovative, affiliate-GPO in an effort to reduce costs. The OIG emphasized that because the traditional GPOs that these affiliate hospitals and facilities were already using did not offer the specialty services, they were left to negotiate the specialty product and services lines on their own. That is, unless the affiliate hospitals and facilities were permitted to take advantage of the services offered by the affiliated Requestor.

This Advisory Opinion is a reflection of the evolving health care models into increased outsourcing of personnel and incorporating more health technology into medical practices. These modern models help to cut costs in a time when traditional hospitals have been struggling to stay afloat. Whereas some of the regulatory limitations required for safe harbor protection may have discouraged affiliate entities from venturing into cost-effective and innovative business models in the past, this new guidance from the OIG opens the door for health care affiliate entities to venture more comfortably into cost effective and innovative offerings.

Submitted by: Jocelyn Ezratty, Esq., Di Pietro Partners, LLP

FRAUD AND ABUSE UPDATES

OIG Portfolio Highlights Hospice Fraud and Quality-of-Care Concerns

On July 31, 2018, the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services released a portfolio titled “Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity” (the “Portfolio”).³

The Portfolio provides 15 recommendations to the Centers for Medicare & Medicaid Services (“CMS”) regarding hospice oversight based upon a review of the Medicare hospice benefit and hospice care generally since 2005. Notably, the Office of Evaluation and Inspections conducted the study, as opposed to the Office of Audit Services, indicating that the study was a broad, investigative look into the hospice industry rather than a more focused review typical of an OIG audit assessment. The study examined prior OIG evaluations and audits of billing and quality of care, as well as investigations of hospice-related fraud cases.

The Portfolio highlights the growth of hospice utilization and reimbursement over the last decade, and describes OIG’s findings with respect to the adequacy and quality of hospice services provided to Medicare beneficiaries. The Portfolio also highlights the importance of providing adequate education to hospice patients and their families and caregivers about the CMS hospice benefit. While OIG acknowledges that not all hospice care facilities have the vulnerabilities identified in this Portfolio, it is important for stakeholders to review the concerns and recommendations expressed by OIG in the Portfolio in order to get a full picture of the government’s stance and to evaluate their services for any of the identified deficiencies that may subject them to enforcement risk.

Compliance and Enforcement Considerations

The Portfolio demonstrates continued scrutiny of hospice services by the government and represents a trend toward ongoing government enforcement against the hospice industry. Therefore, to mitigate risk, it is important that the hospice industry consider the government's current focus, as outlined below, and incorporate mitigation efforts into corporate compliance programs. The key risk areas include the following:

Specific Service Considerations

The Portfolio focuses on the provision of and billing for varying levels of care as well as evaluation of the care setting. The Portfolio indicates that hospice providers performing solely routine services are under more intense scrutiny than hospice providers providing other levels of care. OIG highlights that between 2006 and 2016, hundreds of hospices provided only routine home care, the most basic level of care, to all of their beneficiaries served throughout the year. This trend is increasing over time. In 2016, over 650 hospices provided only routine home care, which is a 55 percent increase from 2011. When a hospice provider's services are limited to routine home care, the government is concerned that beneficiaries might not have access to the more intensive services they need despite the obligation that hospice facilities provide all services necessary for the management of the patient's illness and related conditions. The Portfolio emphasizes that it is critical that hospice providers also provide general inpatient care and continuous home care when patients need more intensive services. A failure to provide all levels of care to beneficiaries, as well as respite inpatient care to caregivers, could be problematic from the government's perspective. Providers should incorporate awareness of the case mix into their compliance efforts.

OIG also identified significant inappropriate billing by hospices for services not meeting Medicare requirements for the level of care billed. Some hospices billed for inappropriate levels of care and for expensive levels of care that the patient did not need. Specifically, the Portfolio indicates that in 2012 hospices billed one-third of all general inpatient care stays inappropriately, costing Medicare over \$250 million. General inpatient care is the second most expensive level of care, and hospices often billed for it when the beneficiary needed only routine home care. Hospices received an unadjusted daily fixed payment rate of \$672.00 a day for inpatient care instead of \$151.00 a day for routine home care.

A major takeaway from the Portfolio is OIG's particular focus on for-profit hospices providing care to patients in skilled nursing facilities ("SNFs") or assisted living facilities ("ALFs"). OIG maintains a skepticism toward for-profit hospices, and specifically identifies these hospice providers as potential "bad actors." OIG highlights certain data points to support such skepticism, providing that, while for-profit hospices billed 41 percent of their general inpatient care stays inappropriately, nonprofit and government-owned

hospices billed 27 percent of their general inpatient stays inappropriately. Also, based on its findings, OIG stated that hospices were more likely to bill inappropriately for general inpatient care provided in SNFs than in any other care setting. Moreover, OIG believes that hundreds of hospices targeted beneficiaries in certain care settings, such as ALFs, who have long lengths of stay in order to receive higher Medicare payments. Again, OIG specifically draws attention to for-profit hospices whose service and billing practices result in reimbursement levels of thousands of dollars more than nonprofit hospices per beneficiary in ALFs. Similarly, OIG believes that for-profit hospices also target beneficiaries in nursing facilities because these beneficiaries commonly have conditions associated with less complex care, longer stays, and more Medicare payments.

Documentation

Another area of focus in OIG's recommendations is the adequacy of physician attestations, clinical documentation, financial records, and other documents that support claims for reimbursement. The study found that some hospice physicians are not meeting requirements when certifying beneficiaries. In particular, physicians did not explain their clinical findings or attest that their findings were based on their examination of the beneficiary or review of medical records. Relatedly, many physicians were found to have provided patients and their families with incomplete or inaccurate election statements resulting in a lack of clarity among beneficiaries, their families, and caregivers around what beneficiaries are entitled to receive or give up with the election of hospice services.

Medical Necessity and Eligibility and Appropriateness of Benefits

OIG also discovered a number of fraud schemes involving hospices inappropriately billing beneficiaries. For example, OIG identified fraud schemes in which hospice providers paid recruiters to target beneficiaries who were not eligible for hospice care and other schemes in which physicians falsely certified a patient's eligibility for hospice care. Beneficiaries who are inappropriately enrolled in hospice care may unwittingly forgo needed treatment or will not have their services reimbursed as Medicare only pays only for palliative care and not for curative treatment.

Takeaway

The key to mitigating the risks identified in the Portfolio and shielding hospice providers from government enforcement inquiries or actions is maintaining an effective corporate compliance program. Even if a hospice provider already has a compliance program in place, it must be reevaluated based on OIG's recent findings. The compliance program should focus on ensuring that providers are providing the appropriate level of care in the appropriate care

setting. Providers should provide the four levels of Medicare reimbursed hospice care based on each patient's medical need and when appropriate regardless of reimbursement considerations. Physicians must accurately certify a beneficiary's terminal illness and the appropriateness of hospice care. Consequently, hospices need to ensure that claims data is as accurate as possible. Hospices must also make sure that proper education materials on the hospice benefit are provided to their patients and their caregivers.

Quality Program Considerations

A common thread woven throughout the Portfolio is the emphasis that OIG places on the need for increased attention to the quality of hospice care. In particular, OIG describes elements of hospice care where quality is lacking, and attributes some specific quality issues to the current payment methodology used by Medicare for hospice services.

Elements of Hospice Care with Trends of Poor Quality

OIG described specific instances in which evaluations and investigations revealed that hospice services have fallen short of quality care. The Portfolio also notes instances of hospices consistently failing to provide the services identified in the patient's plan of care. OIG stated that adherence to a plan of care for a beneficiary is crucial and that the plans should be individualized and detailed, especially with respect to the scope and frequency of needed services. OIG also provides examples of hospices failing to properly manage a beneficiary's medication, leaving the beneficiary in pain for long periods of time. While the examples of hospices failing to provide quality care are concerning, it appears these reports reflect isolated bad actors in the hospice industry. However, one wonders if the broader skepticism associated with hospice quality of care by OIG can be attributed to a difference in understanding of disease progression and treatment alternatives.

Quality Issues Attributed to Payment Methodology

The Portfolio opines that Medicare's current reimbursement methodology contributes to the issue of poor quality. The Medicare hospice benefit pays for every day that a patient is in care, as opposed to paying for specific services provided to beneficiaries. OIG also expresses significant concern that payment for hospice care is not tied to any quality measures, and recommends that CMS alter the system to tie payment to quality of care. Thus far, CMS has maintained that it does not have the statutory authority to introduce the quality measures that OIG suggests into the hospice payment methodology. However, the discord here could be an indication that a major hospice payment reform could be initiated in the future.

Final Takeaway

In light of the emphasis that OIG places on the quality of care throughout the Portfolio, hospice facilities should be proactive rather than reactive in building a robust quality-oriented program. Stakeholders should monitor the areas of concern identified by OIG and assess the status of these highlighted concerns in anticipation of their possible impact on payment in the future. Stakeholders should also conduct an assessment of their compliance programs to identify any areas of enforcement risk based on the concerns expressed by OIG in the Portfolio.

Submitted by: Kathleen Premo, Member, Epstein Becker & Green, P.C.
Francesca Ozinal, Associate, Epstein Becker & Green, P.C.
Megan Robertson, Associate, Epstein Becker & Green, P.C.

PRIVACY UPDATES

OCR Settles HIPAA Breach Involving Three Boston-Area Hospitals

On September 20, 2018, the Department of Health and Human Services' Office for Civil Rights ("OCR") entered into three separate settlement agreements totaling \$999,000.00 with Boston Medical Center, Brigham and Women's Hospital, and Massachusetts General Hospital. According to OCR's press release, the three Boston hospitals violated HIPAA by inviting ABC film crews onto their premises to film a documentary series without first obtaining authorization from patients.

While both the resolution agreements and the press release do not provide much detail about the nature of the breach, it is clear that OCR is committed to ensuring that the privacy of patients during "their most private and vulnerable moments" remains protected at all times.

These enforcement actions raise important questions about the scope of patients' reasonable expectation of privacy within hospital settings. In the past, the Supreme Court has recognized in various decisions that an individual's reasonable expectation of privacy largely depends on context (i.e., individual expectation of privacy is greater at home or in private spaces than it is in public ones). The reasons why an individual may be at a particular location can also affect whether he or she has a reasonable expectation of privacy. For instance, a hospital patient's expectation of privacy may be very different than that of friends or family visiting the patient at the hospital. In fact, the expectation of privacy can even be different depending on where in the hospital the patient might be (i.e., in the parking lot or reception versus in the examination room). Therefore, hospitals should consider context and the possible need for customized rules when creating policies for allowing television or film crews into their facilities.

The OCR press release and the three resolution agreements are available at: <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/bostoncases/index.html>

Submitted by: Christian Perez Font, Managing Partner, Thinken Legal, P.A.

HHS Contemplates Changes to the HIPAA Privacy Rule and 42 C.F.R. Part 2 to Battle the Opioid Epidemic

The Department of Health and Human Services (“HHS”) will issue requests for information (“RFIs”) in regards to changing the HIPAA Privacy Rule (45 C.F.R. Part 160 and Subparts A and E of Part 164) and 42 C.F.R. Part 2 to allow payers and providers to more effectively fight the opioid epidemic affecting the country.⁴ HHS Secretary Alex Azar noted that the HIPAA Privacy Rule and 42 C.F.R. Part 2 can “get in the way of communities and families working together to combat our country’s crisis of opioid addiction.”⁵ However, some experts argue that changes to the HIPAA Privacy Rule are not required because healthcare professionals have the ability to act in the best interest of their patients, despite many providers avoiding disclosure of patient records without consent due to hyper-cautiousness.⁶

On June 20, 2018, the House of Representatives passed the Overdose Prevention and Patient Safety Act (HR 6082, or the “Act”) which would amend 42 C.F.R. Part 2 to allow providers to disclose substance abuse patient records to other covered entities for purposes of treatment, payment and operations, without patient consent.⁷ As currently drafted, 42 C.F.R. Part 2 prohibits providers from sharing a patient’s substance abuse history without consent in an effort to encourage treatment for substance abuse addiction.⁸ Opponents to the Act argue that its passage jeopardizes the confidentiality of substance abuse treatment and will discourage individuals from seeking such treatment.⁹ Similarly, opponents allege that 42 C.F.R. Part 2 needs stricter disclosure requirements than the HIPAA Privacy Rule because of the pervasive discrimination that exists regarding addiction.¹⁰

Proponents of the Act, including many providers, have requested changes to 42 C.F.R. Part 2 to allow the sharing of substance abuse information among healthcare professionals without patient consent.¹¹ Specifically, providers would like 42 C.F.R. Part 2 to mirror the HIPAA Privacy Rule, which allows providers to share protected health information without patient consent for the purposes of “treatment, payment, and health care operations.”

Regardless of whether HR6082 becomes law, both proponents and opponents of the Act agree that more must be done to combat the Nation’s opioid crisis.

Submitted by: Zachary Merson, Corporate Counsel, Availity, LLC

REGULATORY UPDATES

CMS Extends Enrollment Moratoria in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey For Certain Providers

The Centers for Medicare and Medicaid Services (“CMS”) extended the Medicare enrollment moratoria for home health agencies in Florida, Illinois, Michigan, and Texas and non-emergency ground ambulance providers in Pennsylvania and New Jersey effective July 29, 2018 for an additional six (6) months. Most recently, CMS extended the Medicare enrollment moratoria of home health agencies in Florida, Illinois, Michigan, and Texas and non-emergency ground ambulance providers in Pennsylvania and New Jersey on January 30, 2018.¹²

Section 6401 of the Patient Protection and Affordable Care Act authorized CMS to impose temporary moratoria on the initial enrollment or establishment of new practice locations if the Secretary of CMS determined that such moratorium was necessary to prevent or combat fraud, waste, or abuse with respect to a particular provider or supplier types, particular geographic areas, or a combination of both. In 2013, CMS exercised this authority and imposed moratoria preventing enrollment of new home health agencies and branches in Miami-Dade County, Florida, and Cook County, Illinois, and the surrounding counties.¹³ Simultaneously, CMS imposed a moratorium on enrollment of Medicare Part B ground ambulance suppliers in Harris County, Texas, and the surrounding counties.

CMS exercised its authority to extend the initial moratoria on February 4, 2014, for an additional six (6) months and expanded the moratoria to also preclude enrollment of home health agencies in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan, and surrounding counties, and expanded the moratorium of enrollment of ground ambulance suppliers to Philadelphia, Pennsylvania, and the surrounding counties.¹⁴ CMS further extended the moratoria on August 1, 2014, February 2, 2015, July 28, 2015, and February 2, 2016. When extending the moratoria on August 3, 2016 for an additional six (6) months, CMS expanded the home health agency moratorium statewide for Florida, Illinois, Michigan, and Texas and extended the Part B non-emergency ambulance moratorium statewide in New Jersey, Pennsylvania, and Texas.

Due to the August 25, 2017, Presidential Disaster Declaration for several Texas counties after Hurricane Harvey, CMS lifted the moratorium on non-emergency ground ambulance suppliers in Texas to assist with disaster response.¹⁵ The remaining moratoria prohibiting new enrollment of home health agencies in

Florida, Illinois, Michigan, and Texas and non-emergency ground ambulance providers in Pennsylvania and New Jersey remain in place.

Submitted by: Timothy Wombles, Esq., Associate, Nelson Mullins Broad and Cassel

CMS “Major Proposed Rule” Attempts to Reflect Current Changes in Medical Practice in its Payment Systems

In July, the Centers for Medicare & Medicaid Services (“CMS”) published a proposed rule that addresses a number of topics; namely, changes to the Medicare physician fee schedule (“PFS”) and other Medicare Part B payment policies.¹⁶ These proposed changes could have significant effects on providers and services that are rendered within the increasingly expansive sphere of telemedicine. CMS proposes certain services that would not be subject to the limitations on Medicare telehealth services in section 1834(m) of the Social Security Act, and instead would be paid under the PFS like other physicians’ services. CMS reasons that these services are not considered by it to be Medicare telehealth services.

For example, in the proposed rule, CMS confronts the issue of brief “check-in” services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted. Currently, when these kinds of check-in services are furnished prior to an office visit, they are bundled into the payment for the resulting visit. However, an inconsistency arises when these check-in services do not result in a visit, and thus there is no opportunity for payment of the service to be bundled.

CMS attempts to combat this issue by proposing to pay separately, beginning January 1, 2019, for a “newly defined type of physicians’ service furnished using communication technology.” The proposed code, described as GVC11 (Brief communication technology-based service), would provide that check-in services described above, originating from a related E/M service provided within the previous seven days by the same physician or other qualified healthcare professional, be bundled into the pre- or post-visit time of the associated E/M service and not be separately billable. On the contrary, if the telehealth service is not related to an office visit within the past seven days and does not result in a future office visit or related service, CMS proposes a separate payment for the service. Additionally, CMS would also make separate payments for consultations between professionals performed through communications technology regarding a patient’s treatment.

CMS hopes such changes will aid in advancing its overall effort to “further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies.”

The comment period for this proposed rule ended on September 10, 2018.

Submitted by: Anne L. Kelley, J.D. Candidate, UF Levin College of Law

TRANSACTIONS UPDATES

A New Age for Healthcare Mergers

The pending mergers of Cigna and Express Scripts and CVS Health and Aetna are examples of the ever-changing healthcare marketplace. Both transactions have faced opposition, Cigna and Express Scripts from significant Cigna investor Carl Icahn, who alleged Cigna was overpaying for a company that faces an uphill battle, and CVS Health and Aetna, from California Insurance Commissioner Dave Jones, who asked the United States Department of Justice (“DOJ”) to block the merger over concern that reducing competition for Medicare Part D plans would likely result in higher premiums.

Cigna and Express Scripts cleared their largest and final regulatory hurdle on September 17, 2018, when the DOJ approved the proposed \$67 billion merger, which was announced in March and is scheduled to close at the end of 2018. The DOJ determined that the merger would not harm competition in either the insurance or pharmacy benefit manager markets, and does not impede efforts to lower drug prices and increase quality of care. The DOJ said it reviewed more than two million documents and interviewed more than 100 industry experts during its six-month investigation.

Meanwhile, the DOJ’s antitrust review of CVS Health’s \$69 billion bid to acquire Aetna, which would combine a pharmacy, benefits manager, insurer, and retailer with more than 1,000 walk-in clinics across 33 states into one entity, is ongoing. Sources have indicated that the DOJ’s review is taking longer than anticipated due to concern about both companies’ Medicare Part D plans. To ease anti-competitive concerns, it is expected that the DOJ will require CVS and Aetna to divest some of their Medicare Part D assets.

These mergers come on the heels of the DOJ blocking two insurance company mega mergers. In 2016, the DOJ sued to block Anthem’s acquisition of Cigna and Aetna’s acquisition of Humana due to concerns that the mergers would harm consumers by increasing premiums, reducing benefits, and decreasing competition. Unlike the Anthem-Cigna and Aetna-Humana mergers, which

would have resulted in horizontal integration (a reduction from five major insurance companies to three) the Cigna-Express Scripts and Aetna-CVS Health mergers would result in vertical integration, which is less of an anti-competitive risk.

These transactions are taking place at a time when pharmacy benefit managers like Express Scripts are under heightened regulatory scrutiny for their relationships with pharmaceutical companies and providers, as well as their contribution to the ever-rising cost of prescription drugs. It remains to be seen how the proposed merger will impact drug costs and physician relationships.

Large mergers and acquisitions can be expected to increase in volume as healthcare industry veterans leverage their market presence in preparation for new players to enter into the healthcare space, including Amazon, which recently acquired online pharmacy retailer PillPack for \$1 billion.

Submitted by: Erica Mallon, Corporate Counsel, Greenway Health

¹ DEP'T OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL ADVISORY OPINION No. 18-07 (July 20, 2018), *available at* <https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-07.pdf>.

² 42 C.F.R. 1001.952(j).

³ *Id.*

⁴ See Fred Donovan, *HHS Pushes for Changes to HIPAA Privacy Rule, 42 CFR Part 2*, HEALTHIT SECURITY (Aug. 9, 2018, 11:20 AM), *available at* <https://healthitsecurity.com/news/hhs-to-propose-changes-to-hipaa-privacy-rule-42-cfr-part-2>.

⁵ See Marianne Kolbasuk McGee, *HHS Weighs Changes to Health Data Privacy Regulations*, GOVINFO SECURITY (Aug. 1, 2018), *available at* <https://www.govinfosecurity.com/hhs-weighs-changes-to-health-data-privacy-regulations-a-11271>.

⁶ *Id.*

⁷ See *supra* note 4.

⁸ *Id.*

⁹ See Deborah Reid & Mark Parrino, *Relaxing Patient Privacy Protections Will Harm People with Addiction*, THE HILL (July 22, 2018, 11:00 AM), *available at* <http://thehill.com/opinion/healthcare/398077-relaxing-patient-privacy-protections-will-harm-people-with-addiction>.

¹⁰ *Id.*

¹¹ See *supra* note 4.

¹² Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations, 83 Fed. Reg. 4,147 (Jan. 30, 2018).

¹³ Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Temporary Moratoria on Enrollment of Ambulances Suppliers and Providers and Home Health Agencies in Designated Geographic Areas, 78 Fed. Reg. 46,339 (July 31, 2013).

¹⁴ Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of New and Extended Temporary Moratoria on Enrollment of Ambulances and Home Health Agencies in Designated Geographic Locations, 79 Fed. Reg. 6,475 (Feb. 4, 2014).

¹⁵ Medicare, Medicaid, and Children’s Health Insurance Programs: Announcement of Decision to List the Temporary Moratorium on Enrollment of Non-Emergency Ground Ambulance Suppliers in Texas, 82 Fed. Reg. 51,274 (Nov. 3, 2014).

¹⁶ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program, 83 Fed. Reg. 35,704 (July 27, 2018), *available at* <https://www.federalregister.gov/documents/2018/07/27/2018-14985/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>.