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Health Care Reimbursement and Payor Dispute Update

POLSINELLI REIMBURSEMENT TEAM QUARTERLY NEWSLETTER

The Deregulation Initiative: Further Squeezing of Federal Agencies by way of the Congressional Review Act

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From the outset of his campaign, President Trump made it clear that one of his directives, as the head of the Executive Branch, would be to rollback and/or limit the rules, regulations, policies and other types of guidance pieces issued by federal agencies (*i.e.*. deregulation), because of the financial burdens and operational hurdles that these publications have on private industries. The Trump Administration has consistently maintained that deregulation will (and already has as some may argue) unleash businesses and innovators to more freely function in the economy, thus, resulting in lower consumer prices, more jobs and access to greater innovative products and services.

One manner in which this Administration attempted to reduce regulation and control regulatory cost was through Executive Order 13771, issued on January 30, 2017. The main purpose of this Order was to ensure that for every one new regulation issued by an agency, at least two prior regulations be identified for elimination. This commonly became known as the "one in, two out" rule. Now, to further this Administration's mission of deregulation, on April 11, 2019, the Office of Management and Budget ("OMB") issued a Memorandum to the heads of the executive departments and agencies regarding how this Administration expects agencies to comply with the Congressional Review Act ("CRA").

The CRA, enacted in 1996, is a tool that Congress may use to overturn a rule issued by a federal agency. The CRA requires agencies to report on their rulemaking activities to Congress and provides Congress with a special set of procedures under which to consider legislation to overturn those rules. This Memorandum not only expands on the definition of "rule", but provides that agencies now submit "rules" to the Office of Information and Regulatory Affairs ("OIRA") prior to the rules being sent to Congress for review. OIRA screens all rules passed to it in order to determine whether the rules will need consideration by Congress.

Previous administrations more narrowly interpreted the definition of "rules" in a manner that did not include guidance pieces such as instructional documents, FAQs and letters interpreting regulations. As a result of the narrow interpretation of the definition of rules, many guidance

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July 15 - 16, 2019. Washington, D.C.
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September 4 - 6, 2019. Greensboro, GA
Speakers: Ross Burris -Shareholder, Polsinelli; Ross Sallade - Shareholder, Polsinelli

Webinars

Structuring Investments and Doing Deals in AI in Health Care
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Joining Law and Data Rights
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AI, Blockchain & Smart Contacts in Health Care
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pieces did not need consideration by Congress and, instead, were released directly to the public. However, the Trump Administration, through this Memorandum, has made it clear that it will be defining "rules" expansively to include the aforementioned types of guidance pieces. Therefore, it is likely that most, if not all, guidance pieces are to be considered as rules and must pass through OIRA for determination as to whether Congressional review is necessary.

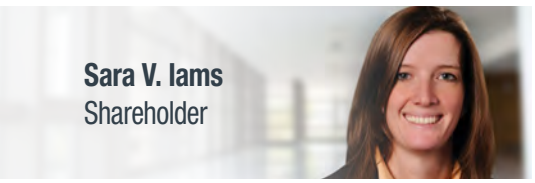
For better or worse, the health care industry has come to rely on guidance pieces issued by agencies and sub-agencies like HHS, CMS, HRSA, OCR, DEA, FDA, DOL-EBSA and VA. To illustrate, CMS consistently issues a plethora of guidance pieces like advisory opinions, memorandums, notices, bulletins, directives, news releases and the like for all health care provider types that pertain to Medicare's Conditions of Participation, the Stark Law, prescription drug plans and the billing and coding of services. Because failure to comply with CMS rules and regulations may result in suspension or expulsion from Medicare, overpayment concerns and other false claims issues, the health care industry looks to guidance pieces to ensure compliance with CMS rules.

A byproduct of requiring agencies to submit almost all types of guidance pieces to OIRA in a heightened manner, coupled with the greater scrutiny that these pieces will now be met with, will be that agencies may be less inclined to develop pieces given the time and resources it will take to comply with the Memorandum. Furthermore, agencies will not only need to submit all guidance pieces to OIRA with a recommended designation of "major" or "not major" that includes a thorough analysis of the agencies position, but they will also need to regularly notify OIRA of all upcoming rules and whether they will be proposed as major or not major. After submission, if OIRA determines a proposed rule to be major, then the rule is sent to Congress for consideration.

For rules, which now include guidance pieces under the Administration's expansive definition, to be designated as major, it must: (A) have an annual effect on the economy of $100,000,000 or more; (B) result in a major increase in costs or prices; or (C) cause significant adverse effects. Though the first measure allows for a proposed rule to be evaluated from an objective lens, the second two measures allow proposed rules to be construed through the political biases of decision maker(s) tasked with determining whether the rule is major (*i.e.,* a catch-all). Thus, in addition to the aforementioned hurdles, agencies will now be faced with the irony of having to determine whether their proposed guidance pieces are major rules without the guidance needed to make those determinations itself.

Julius W. Hobson, Jr., a Senior Policy Advisor with Polsinelli, surmises that through this action and many others, it is the overall intent of this Administration to lessen the regulatory burden of the private sector by increasing the burden placed on the agencies. Compounded with the little resources afforded to agencies by the ongoing squeezing of their operational budgets, these orders are purposefully thwarting the agencies' abilities to properly and effectively execute their purposes of regulating private industries.

Space Sharing



After months of unofficial previews and promises of forthcoming relief, CMS published guidance for hospitals that share space with other hospitals and other types of health care providers. The draft guidance presents a new direction for CMS's interpretation of space sharing limitations in favor of increased provider flexibility, and CMS directly acknowledges this shift at the outset of its guidance:

> *"Please note prior sub-regulatory interpretations prohibited co-location of hospitals with other health care entities. This guidance changes that to ensure safety and accountability without being overly prescriptive."*

CMS did not publish this new guidance through formal rulemaking, instead adding it to Appendix A of the State Operations Manual ("SOM"). Despite the informal process, CMS is offering providers an opportunity to comment on the new guidance by July 2, 2019. Comments should be directed to **HospitalSCG@cms.hhs.gov**. CMS expects to publish final space sharing guidance following this comment period.

History

Beginning in 2011, the CMS Survey & Certification group sought to publicly define and enforce its interpretation of the concept of space sharing and the prohibitions it placed on co-located hospital facilities — drawing upon a combination of the Medicare Conditions of Participation ("CoPs") for hospitals and the hospital outpatient provider-based regulations. In essence, the original interpretation prohibited hospitals (including provider-based departments) from sharing almost any space with another hospital or another entity. CMS publicly discussed this position in webinar presentations in 2015 and 2016 and embraced it in provider-based attestation denials that slowly became public. While neither the CoPs nor the provider-based regulations address the space sharing concept in any meaningful way, CMS cited to both to support its interpretation and conclusion that shared hallways, reception desks, waiting rooms and a variety of other spaces were not permitted. Sometimes, the interpretation went so far as to require separate entrances, separate elevators, separate restrooms and even the construction of walls totally bifurcating hospital space from non-hospital space.

This interpretation became part of the standard survey process and review of provider-based attestations (including the review of supporting floor plans) resulting in a number of denials of provider-based status, attempted recoupments and provider appeals. Despite some provider successes on appeals of these denials, the pervasive nature of this interpretation caused hospitals to incur significant build-out costs to fully separate space and reduce survey and provider-based billing risk. Lawyers and other advisors became experts at reviewing floor plans to recommend structural building changes to reduce these risks. Meanwhile, the modern design of open buildings that fostered patient-centered care delivery models and allowed patients to move easily from a physician office to a hospital outpatient department for imaging, therapy or other services was thwarted in most multi-use buildings.

I. New Draft Guidance – What Is Addressed

CMS intends for this new guidance to permit patient care pathways (literally) that promote patient convenience and flexibility of provider partnerships without compromising patient safety, quality or privacy. Generally, the new guidance appears to offer relief from the most burdensome and costly "separation requirements" that arose from previous CMS interpretations of the CoPs and provider-based regulations. The guidance covers space sharing, staff sharing, contracted services, emergency services and also discusses how state survey teams should survey for compliance with the new standards.

Space Sharing

The new SOM provisions focus largely on two co-located hospitals, but the new guidance also applies to a hospital outpatient department that is co-located with another health care entity. Though CMS does not directly define "health care entity" for purposes of this guidance, it is

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broadly described and should be read to include entities that are surveyed independently (*e.g.,* IDTFs, ASCs, rural health clinics) as well as those that are not (*e.g.,* physician offices).

The new guidance clearly limits space-sharing in clinical spaces. The use of the term 'clinical spaces' is the crux of the new SOM provisions, and the basis for CMS's significant departure from its prior space sharing interpretations. Under the draft guidance, a hospital (including provider-based outpatient departments) must have distinct spaces for clinical operations over which the hospital maintains control at all times. The guidance describes these distinct spaces as clinical spaces designated for patient care, including outpatient medical clinics, nursing units (including exam and procedure rooms located in nursing units), laboratories, pharmacies, imaging centers, operating rooms, post anesthesia care units, emergency departments, etc. CMS states that co-mingling hospital and non-hospital patients in a clinical space could pose a risk to infection control, patient safety, patient privacy and confidentiality of medical records.

In a significant departure from its prior interpretation, CMS now suggests that hospitals and their co-located health care entities may share non-clinical spaces and pathways, including:

- Hallways (as long as the hallways that connect hospital clinical spaces to non-clinical are separated by distinct entrances)
- Walkways
- Patient Waiting Rooms
- Restrooms
- Reception Desks (as long as there are separate check-in spaces and signage)
- Staff Lounges
- Elevators
- Main Building Entrances

The guidance also requires that public paths of travel (*e.g.,* hallways with distinct entrances to departments such as laboratory, pharmacy, etc.) be well-marked so that the public may know which health care entity is performing services in which department.

While the draft guidance offers significant relief from the prior CMS view that space sharing was generally prohibited, some of the operational questions still remain. For example, how distinct must a distinct entrance be? Is a closed door required or will an entryway with clear signage suffice? That answer may be fact-based to some extent, depending on location of the entrances and how close the hospital's clinical space is to the non-hospital space. Additionally, may a single person staff both sides of a reception area as long as the hospital and non-hospital areas are clearly defined? The guidance would appear to permit this, as the reception areas are not generally part of a clinical space. The hospital must still comply with the provider-based regulations pertaining to public awareness, but proper signage, separate admission forms and clear patient direction could be operationalized to meet those rules.

The CMS guidance cannot be drafted to address every possible issue. Providers must view the guidance as a whole, making arguments in line with the general themes for CMS:

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non-hospital patients should not traverse through hospital clinical space to ensure hospital patient safety, infection protection, privacy and confidentiality.

Staff Sharing

CMS's guidance also addresses arrangements where a hospital may share clinical staff with a co-located health care provider. Such arrangements are commonly sought as a means to promote provider efficiency and eliminate clinical staff down time. For providers seeking this type of arrangement, CMS notes that hospitals must independently meet Medicare CoP staffing requirements and cannot, for example, furnish compliant nursing coverage if the nursing staff is not fully dedicated to the hospital for a specified shift. Essentially, clinical staff may not work at one hospital while on-call for another, float between two hospitals or a hospital and another health care entity, or otherwise furnish services simultaneously to a hospital and another health care entity. This guidance would not apply to physicians who may be on the medical staff of two or more hospitals if they are privileged and credentialed at each. CMS does not define "shift" in this guidance, but shifts are generally well-defined by hospitals, particularly for nurses and other non-physician clinical staff. Those shifts could be different; however, for a hospital outpatient department.

CMS does not address specific provider-based regulatory requirements, but nothing in this new guidance would abrogate any CMS requirements for the maintenance of provider-based status, including administrative and operational integration or the special rules applicable to staffing in provider-based departments that are operated under management contracts.

Contracted Services

Separate from contracting for staff, the draft guidance also addresses contracted services between co-located entities more broadly. While a co-located hospital is individually responsible for compliance with the CoPs, CMS states that hospitals may obtain services under arrangements from a co-located hospital or health care entity and need not notify patients that such services are obtained under contract. CMS considers these services to be provided under the oversight of the hospital's governing body, and they are treated as any other service provider directly by the hospital.

In prior informal interpretations, CMS clearly identified services that a co-located hospital was *permitted* to share with a host versus those it was *prohibited* from sharing. With one notable distinction, the draft guidance mirrors the prior interpretations with respect to *permitted* contracted services, listing the following examples: laboratory, dietary, pharmacy, maintenance, housekeeping, security, food preparation and delivery, fire detection and suppression, medical gases, suction, compressed air and alarm systems. The notable distinction is pharmacy, which appeared on the *prohibited* list in at least one historic CMS document. This draft guidance does not identify other services that a co-located hospital is *prohibited* from sharing with a host, a list that historically included respiratory services, nursing and medical record department services, discharge planning, and quality and infection control programs. Whether CMS clarifies the scope of prohibited contracted services in the final SOM provisions remains to be seen.

Based on the survey procedures, hospitals must maintain a complete list and current copies of all contracts for services obtained by the hospital. The hospital must also ensure that the governing body maintains full oversight over all services that the hospital obtains through contracts with other entities.

Emergency Services

In an apparent addendum to existing SOM guidance under the governing body CoP (42 C.F.R. § 482.12(f)), CMS also dedicates considerable attention to emergency services requirements for a hospital co-located with another hospital or health care entity that does not have its own emergency department. The purpose is to ensure that these hospitals (and hospital departments) have the independent capability, and corresponding policies and procedures, to appraise and perform initial care in an emergency rather than relying on a co-located health care entity to respond. According to CMS, the policies should: (1) identify when a patient is in distress; (2) state how to initiate an emergency response (*e.g.*, calling for staff assistance and the on-call physician); (3) describe how to initiate treatment (*e.g.,* CPR and the use of an Automated External Defibrillator (AED); and (4) recognize when the patient must be transferred to another facility to receive appropriate treatment. From a practical perspective, this also means having procedures in place to contact an appropriate emergency department when necessary; whether at the host or elsewhere, and, if at the host, establishing a safe mechanism to initiate the transfer.

The draft guidance permits co-located hospitals without an emergency department to contract with a host for staff to provide the appraisal and initial treatment of

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patients in an emergency, although the staff must be dedicated to the hospital and not on-duty simultaneously at the host or other health care entity. Interestingly, CMS also makes the following unexplained statement:

> *"Hospitals without emergency departments that contract for emergency services with another hospital's emergency department are then considered to provide emergency services and must meet the requirements of EMTALA."*

While CMS does not make a clear distinction, this would appear to apply only in circumstances when a co-located hospital contracts for the host to provide a complete emergency department under arrangements; it would not apply simply by virtue of contracting with the host hospital for staff to provide the appraisal and initial treatment of patients in an emergency.

Finally, this guidance does not change a hospital's obligations under EMTALA when the hospital has an emergency department. It also does not change the provider-based regulations, which differentiate between (i) on-campus outpatient departments and off-campus dedicated emergency departments (requiring compliance with EMTALA); and (ii) other off-campus departments (not requiring compliance with EMTALA). Under the CoPs; however, these other off-campus departments must have the policies and procedures addressed in this guidance and may not comply through an ad hoc contractual arrangement with another co-located hospital or health care entity.

Survey Guidance

The draft SOM guidance directs surveyors to obtain a floor plan to determine how co-located space is used (and by whom) and a list of all services that a hospital obtains through contracts with others, including the hospital or other health care entity with which it is co-located. The floor plan should delineate which space is used by the hospital and for what services, clearly identifying the locations of both required and optional hospital services. The hospital should make clear the pathways for patients to ensure that non-hospital patients do not travel through hospital clinical space.

CMS is clear that any violations uncovered in the survey process (where there are two surveyed/certified providers involved) would create violations for both providers, and the surveyors should file a complaint regarding the other provider (*i.e.,* the provider not originally the subject of the survey) to ensure a survey process for the second provider. For example, CMS notes that the shared use of clinical space by two or more separate health care entities can potentially lead to non-compliance with the CoPs related to nursing, infection control and patient's rights under 42 C.F.R. sections 482.13, 482.23 and 482.42.

II. New Draft Guidance – What Is Not Addressed

Though the guidance addresses a number of core space-sharing and co-location concerns, there are a few topics that CMS left untouched:

1. **Lease of Space to Specialty Physicians in Rural Areas:** Though CMS personnel have recently suggested that this practice should not be prohibited, particularly in rural areas, the guidance does not address the concept of leased space within hospital outpatient departments by specialty physicians. This practice, particularly for rural providers, is often the only economical method to bring specialists to certain geographic areas as these specialty services generally only need one or two days per month. Nothing in the draft guidance should be read to limit this practice, as long as the non-hospital patients do not travel through the hospital's clinical space in order to see the specialist in the leased space. But, some direct CMS confirmation of this practice in the final guidance would be useful.
2. **Space-Sharing Restrictions from Other Sources:** The guidance is limited to compliance with the hospital CoPs. To the extent space-sharing is restricted under the Medicare regulations for other surveyed and certified providers and suppliers (*e.g.,* ASCs, RHCs, IDTFs), these provisions are not addressed (or superseded) by this guidance.
3. **Compliance with the Provider-Based Rules:** Nothing in this draft guidance addresses any aspect of the provider-based regulations. But, because the prior CMS space-sharing prohibitions were merely a non-regulatory interpretation of regulations (both provider-based and CoPs) that in no way addressed space sharing, this new "interpretation" of the CoPs should limit continued proliferation of the prior space-sharing interpretation. It is unclear; however, whether and how this new CMS interpretation of the hospital CoPs will be implemented by the MACs and CMS Regional Offices in considering provider-based attestations.
4. **Dealing with Prior Denials, Recoupments and Build-Outs:** For providers in the middle of appeals related to space sharing issues, this guidance should provide an opportunity for renewed dialogue with CMS regarding the denial, but the guidance does not provide direct encouragement or pathways to do so. To the extent that CMS has recouped payments under the provider-based regulations on the basis of space-sharing "violations" that are permitted under the new guidance, it may be possible for providers to re-visit those results with CMS.

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Additionally, for those providers still in a position to reverse unnecessary build-outs for space separation, discussions with CMS (via the comment process) or with the MACs should be considered.

III. Key Questions for Providers

Now that CMS's guidance is here, how should providers adapt their current practices to CMS's new position on space sharing? Provider should consider some key questions:

How does this new guidance impact my hospital's co-located facility strategy? Providers with existing provider-based (or other shared facility) development projects have the opportunity to adjust mid-development or design from the outset new space that aligns with CMS's more lenient interpretation of the space-sharing restrictions. This new guidance creates options for facility design and construction to improve patient access, convenience, and synergy between co-located health care providers.

Does my hospital currently have any shared space, staffing arrangements or contracted services that do not meet CMS's new requirements? This new guidance fairly and clearly states the current CMS interpretation of the CoPs and other requirements with regard to space sharing. This new guidance does not have the force of law, but it is likely to serve as the basis for co-located facility surveys moving forward. Consequently, providers should evaluate their existing facilities to ensure they meet CMS's new standards.

Are there any ongoing CMS survey issues that this new guidance may resolve? The draft guidance comes at a time of heightened enforcement of provider-based compliance criteria. For providers with existing recoupment demands or other ongoing issues with CMS related to space sharing issues, this guidance may offer relief from the prior, hardline interpretation of these requirements.

Do I have a plan to demonstrate provider-based compliance when the surveyors arrive? Nothing in this new guidance indicates that CMS plans to stop surveying for provider-based compliance. And the new guidance highlights the importance of having a plan in place to respond to CMS questions regarding compliance with these requirements. Providers should take time to ensure they have a plan in place to respond to surveyor's questions, including detailed floor plans delineating shared provider spaces and the use of those spaces.

Local Coverage Determination & False Claims Liability:
Binding Legal Authority or Reimbursement Guidance?

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The Medicare program's Local Coverage Determination ("LCD") system allows private entities to make rules that arguably carry the force and effect of law, resulting in serious legal and policy concerns. Setting aside the dubious constitutional status of private contractors engaged in Medicare rulemaking, some courts have recognized that LCDs constitute more than mere guidance and that noncompliance may form the basis for False Claims Act ("FCA") liability.[1] Hospitals, physicians and other health care providers are often unaware of these "laws" and LCDs can be "gotcha" rules raising fundamental questions on fairness and creating significant legal exposure for health care providers. The LCD system also creates inconsistency in coverage across different jurisdictions resulting in unnecessary regulatory complexity. In sum, the current LCD system creates inconsistency, confusion and serious legal liability for health care providers.

Do LCDs Carry the Force and Effect of Law?

The Centers for Medicare and Medicaid Services ("CMS") takes the position that LCDs are merely "administrative and educational tools" and provide general "guidance" to beneficiaries and health care providers concerning which items and services will (or will not) be covered.[2] However, the court's opinion in *United States et al. v. Kinetic Concepts, Inc.* is illustrative of the conundrum court's face when confronted with FCA claims based on noncompliance with LCDs.[3] The defendant, Kinetic Concepts, Inc. ("KCI"), is a manufacturer and supplier of vacuum assisted closure ("VAC") therapy devices used to accelerate open wound healing by a method known as Negative Pressure Wound Therapy ("NPWT").[4] Certain LCDs contained coverage criteria for NPWT devices that had been adopted by Durable Medical Equipment Medicare Administrative Contractors ("DMACs").[5] The relator was a former senior vice president of business systems at KCI for several years.[6] The complaint alleged that KCI engaged in fraudulent billing to Medicare in violation of the applicable DMAC's LCD on NPWT.[7] Specifically, the relator alleged that KCI engaged in fraudulent activity by its misuse of what is known as a "KX modifier."[8] A KX modifier is a billing code used to signal to a DMAC that the requirements found in the documentation section of the LCD have been met and the documentation is available within the suppliers' records.[9] If all of the requirements of the LCD are not met, a supplier is permitted to submit additional documentation with its claim in an attempt to justify coverage; however, use of the KX modifier in that situation is prohibited.[10] Additionally, one DMAC had issued specific guidance warning that "adding the KX modifier without ascertaining that all the requirements specified in the policy have been met could be viewed as filing a false claim and potential abuse of the Medicare program."[11] The crux of the realtor's claim was that KCI had been using the KX modifier to "falsely signal to Medicare's automated billing systems that KCI had records to show that the VAC claim billed for met all of the [LCD] criteria."[12] The relator alleged that KCI routinely used the KX modifier to receive payment quickly without regard to documentation and that the modifier was even known at the company as the "Pay Me" modifier.[13]

KCI's argument was essentially that although it may not have complied with the LCDs, LCDs are not formal laws or regulations that can form the basis for an FCA claim.[14] Further, KCI argued that "[the relator's] theory of legal falsity conflates LCD guidance with statutory reimbursement eligibility – whether Medicare should pay for the claim."[15] In support of this argument, KCI pointed to the fact that LCDs are not binding in administrative proceedings by regulation.[16] The court rejected this argument noting that "adopting KCI's argument would effectively authorize KCI to violate LCDs but immunize its violations only because the terms of the LCDs are not included in regulation or statute."[17] The court found that "proper use of the KX modifier is a condition of payment."[18] The court ultimately concluded its analysis on the issue by explicitly stating that "failure to comply with the LCDs may give rise to an FCA claim."[19]

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[1] *See U.S. ex rel. Youn v. Sklar,* 273 F.Supp.3d 889 (N.D. Ill. 2017); *see also United States et al. v. Kinetic Concepts, Inc.,* CV 08-01885-BRO (AGRx), 2017 WL 2713730 (C.D. Cal. March 6, 2017).; *see also U.S. ex rel. Ryan v. Lederman,* No. 04-CV-2483, 2014 WL 1910096 (E.D.N.Y. May 13, 2014).
[2] Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, Rev. 608, August 2015.
[3] *United States et al. v. Kinetic Concepts, Inc.,* CV 08-01885-BRO (AGRx), 2017 WL 2713730 (C.D. Cal. March 6, 2017).
[4] *Id.,* at 1.
[5] *Id.*
[6] *Id.*
[7] *Id.,* at 2.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.,* at 7.
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.,* at 8.
[19] *Id.*

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Conclusion

Despite some piecemeal reforms by Congress over the years, serious legal issues remain as a result of Medicare's LCD system, both for providers and beneficiaries. Constitutional doctrine, principles of political accountability and fundamental questions of justice all mandate that only governmental officials or entities may create rules that carry the force and effect of law. Accordingly, CMS should follow approximately 20 years of bipartisan criticism and recommendations, proceed with eliminating LCDs and utilize only National Coverage Determinations ("NCDs").[20] NCDs are national policy declarations issued by CMS that identify what items or services will or will not be covered by Medicare or provide specific requirements for coverage. Transitioning to a NCD only system would provide much needed clarity in an already complex and high-risk industry. However, for the time being, providers should treat LCDs as binding from a compliance perspective.

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[20] *See* Medicare Payment Advisory Commission, *Report to Congress: Reducing Medicare Complexity and Regulatory Burden*, 1-53 (2001); *see also* U.S. Gov't Accountability Office, *Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities*, GAO-03-175 (2003); *see also* Office of the Inspector Gen., Dep't of Health & Human Servs., *Local Coverage Determinations, supra*, at 1.

Recap of Reimbursement Institute Summit

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Shareholder

This year's **Polsinelli Reimbursement Institute Summit**, held in Nashville, Tennessee on February 26, 2019, in collaboration with PYA, was a great success! We appreciate everyone who attended and/or spoke on panels and provided invaluable feedback to allow us to improve this important event every year.

The Reimbursement Summit allowed professionals from the general counsel, finance, reimbursement/revenue cycle, operations and compliance offices to dive deep into key health care regulatory and reimbursement issues that impact their entities. Attendees came from across the country and from a wide-variety of health care provider types, including hospitals, home health agencies, behavioral health facilities, long term care facilities, SNFs and other-provider spaces. We discussed valuable strategic insights related to some of the highest priority areas affecting health care reimbursement – Government and Private Payer Disputes, Alignment and Incentive Strategies in Value Based Care, Clinical Care Reimbursement, Updates from D.C., Health Care Clusters and Health Care 2.0, Medicare Advantage and Medicare Part D and Reimbursement Issues Arising in Oncology Transactions. We also had a great time networking with our clients, friends and contacts and discussing how each are facing these important issues.

In today's ever-changing health care world, we see our clients trying to do more work with fewer resources but also focusing heavily on their organization's strategic vision for thriving. Few have time for continuing education and finding relevant education that will actually give them tools to help drive their organization's reimbursement goals is nearly impossible. The Reimbursement Summit is structured to meet this need and feedback from the program has confirmed the importance of the event.

Please plan to join us next year in Nashville on ***Tuesday, May 26, 2020. Details to follow, but mark your calendars.***

Industry Spotlight: What Skilled Nursing Facilities Can Expect with the Patient Driven Payment Model

Beginning October 1, 2019, CMS will overhaul Medicare Part A payments to skilled nursing facilities ("SNFs"). The Patient Driven Payment Model ("PDPM") will remove incentives to increase the amount of therapy minutes provided to SNF residents in order to increase payment under the current Resource Utilization Groups, Version IV ("RUG-IV") model and will more accurately reimburse SNFs for actual costs based on specific patient needs. Implementation of the PDPM is fast approaching, and we recommend beginning preparations for the shift.

Summary of PDPM

There are many aspects to PDPM, but below we summarize the key provisions.

PDPM Replaces RUG-IV

PDPM creates a new method for classifying residents, using many more verifiable, resident-centered characteristics. Residents will be classified into a group in five different components:

1. Physical therapy, based on the resident's "Clinical Category" (primary diagnosis for the SNF stay), and "Functional Status" (standardized functional assessments);
2. Occupational therapy, based on the resident's "Clinical Category" and "Functional Status;"
3. Speech language pathology;
4. Nursing; and
5. Non-Therapy Ancillary, based on co-morbidities or use of extensive services.

For each component, the resident's grouping correlates to an adjusted case mix index rate. The combined component rates are added to a non-case mix base rate to establish the resident's per diem payment rate.

Variable Per Diem Payment and Interrupted Stay Policy Introduced

Because the resource use for SNF services is not constant and varies over the length of stay, the PDPM per diem rates will decline with the length stay. For example, for the resident's rates for the PT and OT components decline at day 21 of a resident's stay. By day 98 of a patient's Part A stay at a SNF, the reimbursement rate will be at 0.76 of the initial per diem rate.

In order to deter SNF providers from discharging residents and then readmitting them to reset the variable per diem schedule, CMS will implement an interrupted stay policy, which will combine multiple SNF stays into a single stay where the discharge and readmission happens within a three-day window.

Number of Required Assessments Decreases

CMS will significantly simplify the assessment schedule for SNF residents under the PDPM. Providers only need to perform PPS assessments *twice*: on day five and on discharge, thereby eliminating the required 14, 30, 60 and 90-day assessments. Providers can also choose to complete an Interim Payment Assessment with a change in patient status. Other assessment requirements, such as those mandated under OBRA, will continue to apply.

CMS is implementing a number of changes to the MDS 3.0 assessment tool, including adding ways to capture the SNF primary diagnosis, surgical history, a report of the total therapy minutes for each mode of therapy and interim functional performance of the patient.

Potential Implications

It is difficult to predict the full impact of the PDPM, but providers can expect and plan for a number of implications in implementation.

Therapy Contract Renegotiations

SNFs' therapy contracts may include "material adverse change" provisions that require the contracted parties to renegotiate upon certain changes to laws that negatively impact one or both parties. Therapy providers may argue that PDPM is a material adverse change that will result in lower therapy utilization, thus seek to renegotiate the contractual terms. SNFs may counter; however, that resident therapy requirements will not change under PDPM. Therefore, if providers have been appropriately providing therapy, neither party should see an adverse change. SNFs should communicate with their therapy providers in an attempt to plan for PDPM implementation and to anticipate any potential contractual issues that may arise.

Prior Over-Utilization Concerns

PDPM shifts away from reimbursement based on therapy minutes, CMS will still collect data on therapy minutes. Some providers are concerned that CMS may seek to recoup prior payments if therapy minutes decline dramatically. CMS anticipates some reduction in therapy minutes and implements the variable per diem rate based on that assumption. Thus, both CMS and providers should expect that a

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resident would receive less therapy over the course of a resident's stay. If a SNF is concerned that it has been over-utilizing therapy; however, it should audit its past practices related to the provision of therapy.

Potential Medicaid Reimbursement Changes
Many states use RUG-IV for determining Medicaid Upper Payment Limits (UPL) and removing RUG-IV may disrupt state Medicaid payments. Because PDPM will more accurately pay providers based on patient characteristics, CMS believes payments made under PDPM will ultimately improve the UPL. Nonetheless, providers should monitor Medicaid reimbursements.

Delay in Claim Reimbursement
SNFs are questioning whether the MACs are ready to implement PDPM and whether SNF payments will be delayed. Neither CMS, nor the MACs, have indicated they are not ready to implement the change timely. Nonetheless, providers should do everything they can to train its staff and track PDPM claims carefully. This will allow providers to seek assistance on payment delays as soon as they identify issues.

Changes in Reimbursement by Private Payors and Medicare Advantage Plans
Private payors could attempt to align with aspects of PDPM by adopting PDPM in its entirety or implementing only certain provisions, such as the variable per diem rate. Medicare Advantage plans will be able to decide whether to adopt or incorporate any aspects of the PDPM program into their plans. SNFs should review their payor contracts carefully in order to determine whether payors can make any such changes unilaterally. If a SNF determines that its contractual terms to be amended, we recommend beginning that process as soon as possible.

Shift in Administrative Duties
CMS advertises the reduction in required assessments will reduce SNF provider burden. Particularly because the payment model is patient-centered, SNFs need to be diligent in their documentation of assessments and other required elements in order to support their claims and to avoid potential audit implication down the line.

Although the full implications of PDPM remain to be seen, a major shift is on the horizon, and it is time to get ready.

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