Over the past few years, the government has restricted the development of hospital off-campus, provider-based locations. Provider-based departments (“excepted” under Section 603) and newly constructed facilities (“nonexcepted”). The Centers for Medicare and Medicaid Services (“CMS”) limited reimbursement for nonexcepted facilities to Medicare Physician Fee Schedule rates. CMS continues to tighten the screws on provider-based facilities through reimbursement reductions and increased enforcement of provider-based regulations.

### I. Reimbursement Pressure Grows

#### A. CMS Targets Excepted Provider-Based Departments

Section 603 created bright-line reimbursement rules for hospitals. Excepted provider-based departments would receive full reimbursement under the Outpatient Prospective Payment System (“OPPS”), while nonexcepted facilities’ reimbursement was adjusted downward. Although ambiguity remained for providers in the midst of construction, and for facilities desiring to relocate or expand, there was a general understanding among hospitals regarding the future of provider-based reimbursement.

CMS upset this apple cart in its 2019 OPPS rulemaking by applying nonexcepted facility payment adjustments to excepted facilities. For now, this reduction is limited to a single code, G0463, which covers the standard “clinic visit” at off-campus provider-based departments. CMS expects to save up to $760 million per year once the payment reduction is phased in after two years. These cuts are non-revenue-neutral, meaning that CMS has not adjusted other components of OPPS to make up for lost hospital revenues.

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The American Hospital Association ("AHA") and other parties have sued to stop these cuts, on two primary theories. Despite the ongoing litigation, CMS intends to announce cuts for additional services, meaning more provider reimbursement headaches could be coming soon.

B. CMS Extends 340B Cuts

The Administration announced it would target 340B drug reimbursement for potential payment reductions. Effective January 1, 2018, CMS implemented a nearly 30 percent payment reduction for separately payable Part B drugs provided by excepted provider-based departments – sparing nonexcepted facilities. CMS is embroiled in litigation over this payment reduction.

On December 27, 2018, Judge Rudolph Contreras ruled for AHA and other plaintiffs, finding that CMS lacked statutory authority to implement the payment reductions. Judge Contreras asked the parties to submit briefs regarding potential remedies by January 26, 2019. HHS filed a motion to stay the proceedings due to the government shutdown, so it is unclear when the court will ultimately decide on a remedy, and HHS will likely appeal.

CMS continued its efforts to reduce Part B reimbursement to 340B entities in its 2019 OPPS rulemaking by extending the 30 percent reduction to nonexcepted facilities. This expansion will likely also be challenged in future litigation. The outcome of this litigation will be important for hospitals’ provider-based strategies – particularly for hospitals that created nonexcepted provider-based locations to avoid 340B reimbursement reductions.

II. Enforcement Relief on the Horizon?

Since at least 2011, CMS has claimed that hospital provider-based locations cannot share space with nonhospital facilities, including freestanding physician practices, university space in an academic medical center, or any number of other nonhospital entities. Simple issues, such as a shared hallway, bathroom or waiting area, could lead to denial of provider-based status and attempted recoupment of the facility’s provider-based reimbursement.

CMS has never clearly articulated the legal basis for this position – though for years it has promised additional guidance. In a recent webinar, however, David Wright (CMS director for Quality, Safety & Oversight) previewed forthcoming CMS guidance regarding space sharing at provider-based locations. The news is better than some hospital providers may be expecting.

CMS appears to have softened its stance on space sharing, and announced its intent to focus on space sharing concerns affecting patient health and safety. Space sharing that might have previously raised CMS’ ire (e.g., shared hallways or waiting rooms) may soon be lower priorities for CMS.
enforcement – so long as patient health and safety is not affected. CMS also recognized that rural facilities face additional hurdles, like specialist availability, and suggested these facilities may be granted additional flexibility to design provider-based space around these concerns.

According to Mr. Wright, this guidance is under review at the Office of Management and Budget and should be released in the coming weeks. Meanwhile, here are some key considerations for hospital providers on the eve of a new era in provider-based enforcement:

- **Don’t Throw Caution to the Wind Just Yet.** Although this guidance is expected to offer greater flexibility, it’s not clear how far CMS will go. It may be wise to maintain a conservative position on space sharing until we have a better idea of CMS’ direction. If your hospital can wait to make final decisions regarding the construction or design of a new provider-based facility, remodeling an old facility or other changes, you’ll be in a better position to take advantage of CMS’ new guidance.

- **Ask CMS For Help (But Don’t Get Your Hopes Up).** If your provider-based plans can’t wait for the new guidance, and a conservative course isn’t an option, there are a few alternatives:
  - First, contact your CMS Regional Office (“RO”) and discuss your proposal with the Survey & Certification team. Because new guidance is expected soon, they may be hesitant to offer much assistance, but Mr. Wright indicated that the ROs have been briefed on the new guidance. Mr. Wright encouraged working with the ROs to resolve outstanding questions.
  - Second, if your RO is unwilling to consider the new guidance before its release, consider approaching Mr. Wright’s office directly (the CMS Division for Quality, Safety & Oversight).
  - If all else fails, carefully review Mr. Wright’s comments to the American Health Lawyers’ Association, and craft a reasonable provider-based design with an eye toward any potential patient safety concerns.

- **Prepare for (More) Ambiguity.** CMS’ focus on health and safety-related space sharing concerns is encouraging. With these new standards, however, come new questions for hospitals, such as: “What types of space sharing create a health and safety concern?” and “What does CMS mean by ‘patient health and safety’?” When pressed for an answer to these questions, CMS could not articulate a meaningful test or standard that hospitals might apply. Consequently, hospitals may be left at the mercy of individual surveyors or CMS representatives who will decide these issues case by case.

### III. Commercial Plans Pile On

Recently, we have seen commercial plans prohibit hospital billing for off-campus departments under the hospital’s name, although this practice is permitted by Medicare and is common in the hospital industry. This standard practice is often called “under arrangements” billing, where inpatient and outpatient services are billed by the hospital but are performed at an off-site location or by a third party.

By denying such claims and arguing that such services are not covered as hospital procedures, commercial plans can reimburse these services at a lower rate. So commercial plans have begun to (1) change their internal billing policies to prohibit this billing practice; and (2) assert that under arrangements billing practices are prohibited by providers’ existing contracts. We have also seen commercial plans allege that such arrangements constitute fraud, even though Medicare permits this practice and commercial plans themselves permitted under arrangements billing until recently.

Although each contract is unique, many commercial plan contracts prior to 2017 either explicitly permit under arrangements billing or do not directly address coverage of off-campus location services. We expect more payors to claim that off-campus departments cannot be billed under the hospital’s name, leading to many years of provider/payor litigation before resolution is reached.

### IV. Conclusion

CMS and commercial plans continue to look for ways to reduce reimbursement hospitals receive for services furnished at off-campus provider-based facilities. But there is some relief in sight for provider-based enforcement. Once CMS releases new guidance, hospitals should have a road map to navigate space sharing concerns. Regardless of what new guidance brings, hospitals must stay up-to-date on billing, contracting, reimbursement and survey guidance to develop and maintain competitive provider-based development and reimbursement strategies.

**Stay tuned for CMS guidance on provider-based locations.**
Managed Care Companies (“Payors”) have become extremely aggressive within the last few years in filing litigation alleging provider fraud, particularly against laboratories in the toxicology space. Blue Cross Blue Shield entities, in particular, have been on the attack. Among the arrangements that insurers like BCBS have started to scrutinize are those that purportedly create “pass-through” billing between providers, such as urine toxicology labs, and rural hospitals. The Payors’ allegations revolve around the higher payment rates that hospitals receive for the same lab services than the lab may receive on its own. The confusion often stems from vague language in provider agreements related to this type of billing. A sampling of the types of allegations brought by insurers is set forth below.

For instance, in Blue Cross and Blue Shield of Georgia, Inc. et al. v. DL Investment Holdings, case no. 1:18-cv-01304-MLB (N.D. Ga.), a number of BCBS insurers filed a complaint against various defendants, including a rural hospital and toxicology lab, alleging that Defendants engaged in a scheme to bill for fraudulent laboratory services in violation of contracts between BCBS Georgia and Chestatee Regional Hospital. Chestatee Regional Hospital is a 49-bed rural hospital located in Dahlonega, Georgia. BCBS Georgia permitted Southern Health Corporation of Dahlonega to assign its rights, duties and obligations under its provider contracts to the purchaser defendant. BCBS alleges that after taking control of the hospital, the purchaser and a toxicology lab, which was out of network and located in Florida, agreed to bill BCBS Georgia for tests performed by the lab as if they had been performed at Chestatee Regional Hospital. After the lab performed the tests, BCBS alleges the patient specimens were sent to Chestatee Regional Hospital, where the hospital would also test the specimens. However, BCBS alleges that the additional testing did not provide any clinical value because the laboratory tests that were performed at the hospital were less sophisticated than the tests that had been performed by the lab, and also that providers received test results from the lab rather than the hospital. Additionally, BCBS alleges that most of the patients had never been to Chestatee, but rather the lab specimens were sent to the lab by a nationwide network of providers to whom Defendants were providing kickbacks (as a percentage of BCBS Georgia’s reimbursement to Chestatee). The tests were then billed through Chestatee Regional Hospital because as a rural hospital and an in-network provider, Chestatee was entitled to a higher reimbursement (greater than $1,400) for the testing, whereas the lab would have received less for the same services (typically between $100-$300).

Similarly, in Blue Cross of California et al. v. Sonoma West Medical Center, et al., case no. 2:18-cv-04912-SJO-GJS (C.D. Cal.), BCBS filed a complaint alleging that in March 2017, after the entity managing Sonoma West Medical Center ended its contract, Palm Drive Health Care District (the hospital owner) sought a new management entity. In April 2017, the hospital entered into a new management contract with one of the Defendants. In this matter, BCBS alleges that Defendants represented that laboratory testing was provided by an out-of-network hospital, Sonoma West Medical Center, for inpatient covered members in order to increase the reimbursement on urine toxicology testing. BCBS alleges that Defendants sourced urine samples from a network of referring marketers and providers to whom Defendants paid kickbacks, and those marketing teams told detox and rehab facilities in Orange County that the testing would be performed by a lab in another state. However, BCBS alleges that the samples were sent to that lab, split into multiple portions, and tested at both the lab and Sonoma West Medical Center. By claiming that the testing was performed at Sonoma West Medical Center, Defendants are alleged to have increased the claim amount per test from $32 (the rate for the lab) to $3,500 (the rate for Sonoma West Medical Center). Plaintiffs allege that Defendants represented that the ordering providers had ordered the tests from Sonoma West Medical Center when actually other labs had been ordered to perform the testing, that the insured members were patients at Sonoma West, that Sonoma West had received an assignment of benefits or authorization from the covered members, and that Defendants were collecting insured members’ cost-sharing obligations.

In RightCHOICE Managed Care, Inc. et al v. Hospital Partners, Inc.,
Case No. 5:18-CV-06037-DGK, (W.D. Mo.), a number of insurers brought an action against Defendants alleging that the Board of Trustees at Putnam County Memorial Hospital (PCMH), a 15-bed hospital in Unionville, Missouri, entered into a variety of agreements that allowed Defendants to represent to Plaintiffs that laboratory testing completed at outside laboratories was being performed at PCMH. Defendants allegedly began to submit claims for laboratory testing at PCMH at that time, despite the fact that the laboratory at PCMH was not yet operational. Additionally, Defendants allegedly hired 33 phlebotomists, located around the United States, to process specimens that were tested by the outside laboratories. Plaintiffs allege that classifying the phlebotomists as PCMH hires was intended to make PCMH appear more involved in the processing of specimens than it actually was. The covered members who received the testing did not receive medical care at PCMH, nor were they seen by providers credentialied at PCMH. Defendants allegedly utilized networks of referring health care providers to whom Defendants provided kickbacks in order to obtain high volumes of specimens.

Volume of laboratory tests increased more than 43,000 percent after the alleged scheme was introduced. The arrangement was investigated by the Office of the Missouri State Auditor.

Finally, in Blue Cross & Blue Shield of Mississippi v. Sharkey-Issaquena Community Hospital, et al, case no. 3:17-cv-00338-DPJ-FKB (S.D. Miss.), Blue Cross & Blue Shield of Mississippi filed a complaint against Sharkey-Issaquena Community Hospital (SICH) and various labs. Plaintiff alleged that the laboratory tests for which SICH, a small, rural hospital in Mississippi, submitted $33.8 million in claims were not ordered by a licensed physician or other licensed health professional with staff privileges at the hospital, and were not performed at the hospital but rather at labs in Texas. The lab results were submitted to providers on forms with the labs’ logos but listed the hospital’s CLIA number and address. BCBS alleges that it agreed to a Percentage of Charge reimbursement rate because SICH is a small, rural hospital and would not have agreed to such a reimbursement rate for an outside laboratory. This case appears to have been resolved and dismissed.

While the facts alleged in these complaints are complicated, the essence of each suit attacks the propriety of performing lab testing at one location and billing that work through another. The outcome of these arrangements is yet to be determined as the cases in this space are relatively new and are ongoing. If, however, you have set up this type of arrangement or have questions about them, we would be happy to discuss the impact the aforementioned actions may have on your business.

Commercial payors are highly scrutinizing billing arrangements that purportedly create “pass-through” billing between providers and rural hospitals. What does your provider participation agreement say?
At the beginning of 2019, we are looking back at developments and trends in CMS audits, investigations and appeals that occurred throughout 2018. This article examines some unique audit and investigation strategies that the OIG, along with CMS and its contractors, employed over the past year. We also look at developments related to the Medicare appeals backlog, and some innovative ways that providers are finding some relief from the historically large appeals backlog.

**New and Innovative Audit Strategies**

We continued to see a substantial amount of audit and investigation activity from CMS and its contractors throughout 2018, including from the Unified Program Integrity Contractors (“UPIC”), who have picked up where the old ZPICs, PSCs, and MICs left off, and an uptick in the number of state Medicaid audits and investigations. Combined, this audit activity occurred across the provider spectrum, from small mixed-specialty practices to hospice providers and large national providers and suppliers. Many of these audits were of the standard medical review variety; however, some of them were exceptionally innovative.

In another example, the OIG released a report in February 2018, titled Wisconsin Physicians Service Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply With Medicare Requirements, detailing a review it conducted of claims paid by Wisconsin Physicians Service (“WPS”), the Zone 5 Medicare Administrative Contractor, related to hyperbaric oxygen therapy (“HBO”) services. In the report, the OIG estimated that 85 percent of the HBO claims paid by WPS did not comport with Medicare requirements. Two months later, following a self-disclosure to the OIG, Marquette General Hospital in Michigan agreed to pay $545,663 in a civil monetary penalty settlement based on one of its physicians’ HBO claims.

Based on the OIG’s report, and statistical errors from other hospitals, WPS sent out letters to some HBO providers stating that the OIG had determined that 85 percent of its claims were paid erroneously. While expressly stating that WPS had not done any analysis of the provider’s specific HBO claims, the letter nonetheless suggested that the statistical errors identified in the OIG constituted credible information concerning a potential overpayment. Therefore, under the 60-day rule the provider is required to initiate an internal investigation of its HBO claims and self-report any overpayments it identifies and quantifies.

In another example of hot areas on the OIG and CMS’ radar, the OIG released a report in July 2018 titled Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: an OIG Portfolio. This report found that hospices’ inappropriate billing, ranging from unneeded expensive levels of care to outright fraud, costs Medicare hundreds of millions of dollars. The report makes a number of suggestions to improve the situation, including strengthening hospice oversight and analyzing claims data to identify hospices that engage in questionable practices. One of these areas is physicians falsely certifying patients as terminally ill and failing to discharge ineligible beneficiaries from hospice care.

Within a month of this report being released, we were contacted by a national hospice provider that had investigators from the UPIC for the Midwestern region, NCI – AdvanceMed, show up on its doorstep demanding medical records and wanting to interview employees. This on-site investigation turned out to be related to a post-payment probe audit, which later turned into a full-blown statistically valid random sample, a payment suspension, and placement of the client’s location on a full pre-payment review. The issue that the auditors appear to have homed in on is the same as one of the issues identified in the OIG report: long-term-stay patients that the
UPIC believes have been incorrectly certified as terminally ill.

HHS Is Again Ordered to Eliminate Backlog

On November 1, 2018, a federal court for the District of Columbia again ruled in favor of the AHA in its lawsuit against HHS, *American Hospital Association, et al. v. Alex Azar* (Civil Action No. 14-851), which it originally brought in May 2014 seeking relief from the massive delays occurring in the administrative appeals process for Medicare reimbursement claims; the so-called Medicare Appeals Backlog.

Initially, the District Court declined to intervene, stating that it did not have jurisdiction to issue a writ of mandamus, and that Congress and HHS, rather than the courts, should fix the problem. On appeal, the D.C. Circuit Court of Appeals found that the court did have mandamus jurisdiction and ordered the District Court to determine whether compelling equitable grounds existed to issue a writ of mandamus, which it determined did in fact exist. The District Court then ordered HHS to reduce its backlog of Medicare appeals at the ALJ level. The order by U.S. District Judge James Boasberg requires HHS to reduce the appeals backlog, using its own projected fiscal year 2018 backlog of 426,594 appeals as a starting point, by 19 percent by the end of FY 2019; 49 percent by the end of FY 2020; and 75 percent by the end of FY 2021; and eliminate the backlog by the end of FY 2022. HHS did not appeal the judge’s ruling in the case.

The judge’s ruling also requires HHS to provide quarterly status reports beginning December 31, 2018, to update the court on its progress in reducing the Medicare appeals at the Administrative Law Judge level. According to the most recent report filed by HHS, there were 417,198 appeals pending at the end of the fourth quarter of 2018 compared to more than 886,000 appeals pending in 2015. In addition, Recovery Audit Contractor appeals declined from nearly 50,000 at the end of 2015 to 774 in 2018.

"The report found that hospices’ inappropriate billing, ranging from unneeded expensive levels of care to outright fraud, costs Medicare hundred of millions of dollars."
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for which it has no adequate remedy at law; (3) that greater injury will result from denying the temporary restraining order than if it is granted; and (4) that a temporary restraining order will not disserve the public interest.” The court ultimately determined that the provider had satisfied these factors and issued a TRO preventing HHS from recouping further payments until the case had been determined by the ALJ.

Similarly, Adams EMS sought a TRO against the recoupment of $401,611 prior to its appeal before the ALJ, under the basis of the deprivation of its due process rights. Supported by the legal framework outlined in *Family Rehabilitation*, the Adams EMS court evaluated the four factors for issuing a TRO. The court first ruled that the company had a property interest in its earned Medicare payments, and that this property interest was being violated by HHS’ failure to timely adjudicate the administrative appeal of the overpayment determination. Furthermore, because Adams EMS was already forced to lay off most of its employees and likely faced bankruptcy or closure because CMS recouped the alleged overpayments while it awaited its ALJ hearing, the court found that it would be irreparably harmed absent injunctive relief. On the other hand, HHS would be minimally harmed if it were prevented from recouping the payments by the Court issuing a TRO. Finally, the court held that it would be against the public interest if Adams EMS was forced to stop operating and no longer provide ambulance services to patients in need. Finding that all four factors weighed in Adams EMS’ favor, the court ruled that issuing a TRO was the only way to adequately protect Adams EMS while it waited on its administrative appeal.

These cases offer a glimmer of hope for many providers facing extraordinary hardship resulting from the massive Medicare appeals backlog. Courts appear to be sympathetic to the plight of many providers seeking injunctive relief as a way to continue to operate while navigating the banalities of the current Medicare appeals process. While these cases give providers a potential framework for obtaining injunctive relief, they still have significant hurdles to prove while seeking a TRO, including the specter of financial ruin if recoupment payments continue. Nevertheless, these cases provide a precedent that was not previously available to providers and, if used correctly, may shelter needy providers and their employees while they await their day in court.

We will continue to track the Medicare appeals backlog.
Why You Should Attend the 2019 Reimbursement Summit

On February 26, 2019, Polsinelli’s Reimbursement Institute will present its Third Annual Reimbursement Summit, in collaboration with PYA. Join us at the Omni Nashville Hotel for this one-day, must-attend educational and networking event! Unlike other continuing education events, the Reimbursement Summit allows health care professionals from the general counsel, finance, reimbursement/revenue cycle, operations, and compliance officers to dive deep into key regulatory and reimbursement issues that impact and make or break the success of their health care entities. Whether you come from the hospital, home health, behavioral health, long-term care, ASC, physician practice, pharmacy or other-provider space, this seminar will be highly relevant to you and will allow you to go back to your organization with valuable strategic insights related to some of the highest-priority areas impacting health care reimbursement now and in the future.

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 in the future. 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 help meet this need.

Join us to hear health care reimbursement experts from Polsinelli, PYA and top health care institutions share in-depth strategic information pertaining to:

- **Government and Private Payor Disputes** – Government and commercial payors alike have not slowed their use of audit and recoupment, and indeed, both have found new ways to rectify what they view as provider misdeeds. Panelists will discuss the top trends and strategies in payor disputes, all of which can have a significant impact on the financial stability of health care organizations. Our experts will provide their strategic insights on areas such as using TROs to prevent recoupment, responding to denials or reversals of provider-based determinations, responding to audits and post-audit requirements, responding to and managing the downstream impact related to the increased use of CMS revocations, and more.

- **Clinical Research Reimbursement** – Panelists will go in-depth into the clinical research life cycle, from funding to clinical trial reimbursement, allowing participants to target and avoid key risk areas in this complicated regulatory framework, and allow your entity’s clinical research group to thrive.

- **Reimbursement Trends in Behavioral Health Care** – The behavioral health landscape is experiencing tremendous growth and change. Experts will discuss government and private reimbursement trends across the spectrum of hospital-based and freestanding behavioral health providers, including a review of recent legislation, reimbursement strategies under mental health parity laws, and audit strategies and pitfalls.

- **2019 Congressional and Policy Update** – Polsinelli and PYA public policy experts will discuss the current political landscape, potential changes since the 2018 election, and the potential effect on reimbursement.

- **Alignment and Incentive Strategies in Value-Based Care** – Expert panelists will explore major trends and themes in alignment and alternative payment models from both the payor and provider perspectives, including evaluation of incentive goals and alternatives to common alignment and value-based arrangements to strengthen your institution’s financial success.

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The 2019 Medicare Physician Fee Schedule Final Rule ("the final rule") announced broad changes to policies governing the Medicare Part B payment of evaluation and management ("E/M") services delivered in the physician office and outpatient settings.

These reforms were made as part of the Centers for Medicare and Medicaid Services’ overarching strategy to reduce regulatory burdens on health care providers. The reforms are wide-reaching because E/M visits are among the most commonly billed service in both the physician office and outpatient settings. According to CMS, E/M services comprise approximately 40 percent of allowed physician fee schedule charges across all settings, and approximately 20 percent of allowed physician fee schedule charges in the physician office and outpatient settings. The final rule’s reforms to documentation and payment of E/M services are limited to E/M services furnished in the physician office and hospital outpatient settings.

There are five levels of E/M services covered in the physician office and hospital outpatient settings. The E/M services increase in clinical complexity from Level 1 through Level 5. As the service level increases, so does the payment amount for the service. In most instances, practitioners document each E/M service using the 1995 or 1997 version of the E/M Documentation Guidelines (collectively, "the documentation guidelines"), which require that information about the patient’s history, the physical examination of the patient, and the medical decision-making process be recorded in the patient’s medical record to support the coverage and payment of the appropriate E/M service.

After the seminar, we will hold a reception at the Omni, allowing panelists and participants to network, ask questions, and enjoy friends and contacts.

We hope you will join us in person for the Reimbursement Summit, and by webinar for the Health Care Reimbursement 101 session.

For details, go to polsinelli.com or contact Sinead McGuire at 303-583-8278.
CMS announced proposed reforms to the documentation standards and payment policies for E/M services in July 2018 when it released the 2019 Medicare Physician Fee Schedule Proposed Rule. If finalized in their entirety, the proposed policies would have made sweeping reforms to the documentation and payment of E/M visits beginning in 2019. The proposed rule would have consolidated the payment for Level 2, Level 3, Level 4 and Level 5 E/M services into a single payment rate instead of providing for a distinct level of payment for each service. Level 1 E/M services would have retained a separate payment rate. The proposed rule would have also reduced E/M documentation requirements for billing practitioners.

The press release accompanying the proposed rule quoted CMS Administrator Seema Verma, who supported the wide-ranging proposals by stating they “deliver on the pledge to put patients over paperwork by enabling doctors to spend more time with their patients.” Nevertheless, the proposals did not receive overwhelmingly positive feedback in the notice-and-comment process and CMS moderated the policies it will implement when it releases the final rule. The majority of these reforms will go into effect in 2021, but some changes to the documentation standards went into effect January 1, 2019. Effective January 1, 2019, CMS implemented slight changes to the documentation standards for E/M services, which continue the Agency’s response to feedback from the provider community addressing the E/M documentation burden. E/M services must still be documented under the 1995 or 1997 documentation guidelines, but both of the 2019 reforms relieve practitioners from re-entering information already included in a patient’s medical record when: (i) the practitioner is treating an established patient and the information is included in the patient’s medical record from a previous visit; and (ii) information about a new or established patient’s medical history or primary complaint has already been entered in the patient’s medical record by an ancillary provider or the beneficiary and the practitioner indicates they have reviewed and verified the information.

The remaining reforms made in the final rule are effective on January 1, 2021. Instead of adopting the proposed rule’s approach of consolidating Level 2 through Level 5 E/M services into a single payment rate, the final rule requires separate payment rates for Level 1 and Level 5 E/M services. Level 2, Level 3 and Level 4 E/M services will be consolidated into a single payment rate. CMS reasoned that making a separate payment rate for Level 5 E/M service was appropriate in response to comments expressing concerns about the needs of patients with complex medical conditions.

Practitioners will also have the opportunity to take advantage of documentation reforms in 2021. Currently, a practitioner must continue to document E/M visits using the 1995 or 1997 documentation guidelines. This means the practitioner must include information within all three domains of the documentation guidelines – patient history, physical examination, and medical decision-making – to support payment for the appropriate E/M service. Beginning January 1, 2021, a practitioner may continue

to use the complete 1995 or 1997 documentation guidelines to support care, may elect to document information within only medical decision-making criteria domain, or may use time-based criteria to support payment for each E/M service billed. The documentation flexibility standards apply to Level 2 through 5 E/M services, and any E/M service reported at Level 2, 3, and 4 can be supported with Level 2 documentation. Since Level 5 services are paid separately, the practitioner will be required to provide the necessary documentation to support a Level 5 E/M service using any of the approved methods.

CMS will also implement two types of add-on codes beginning in 2021 that can be reported in conjunction with a Level 2 through Level 4 E/M service. First, CMS finalized two new add-on codes that can be billed for inherently complex services provided through primary care (HCPCS code GPC1X) or nonprocedural specialty visits (HCPCS code GCG0X) for new or established patients. These add-on codes are intended to address the inherent complexity
of E/M services in primary care and nonprocedural specialties. The add-on code descriptor for nonprocedural specialty visits identifies endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, nephrology, infectious disease, psychiatry, pulmonology, and interventional pain management-centered care as potential visit types eligible for the add-on.

Second, CMS finalized an add-on code that may be billed to reflect additional resources that are provided to a patient during an extended E/M service. The add-on code uses the overall duration of face-to-face time during the visit to define whether the visit qualifies as an “extended” visit. E/M visits that are reported between Level 2 and Level 4 are eligible for the extended payment add-on when face-to-face time is between 34 and 69 minutes for an established patient and between 38 and 89 minutes for a new patient.

The cumulative effects of the reforms to E/M services documentation and payment are significant because of the prevalence of E/M services provided in hospital outpatient and physician office settings. However, the 2021 implementation of the major documentation and payment reforms offers providers a chance to prepare for and predict the potential operational and financial effects of the changes.

We are working hard to help you