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Reimbursement and Payor Dispute Update

POLSINELLI REIMBURSEMENT TEAM NEWSLETTER

Key Takeaways of the Part I Interim Final Rule for the No Surprises Act

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On July 1, 2021, the Departments of Health and Human Services ("HHS"), Treasury, and Labor, along with the Office of Personnel Management (collectively the "Departments"), issued the first tranche of regulations implementing the No Surprises Act ("NSA") titled "Requirements Related to Surprise Billing; Part I" (the "Part I IFR"), and requested stakeholder comments on a handful of issues in the Part I IFR. This article describes some of the Part I IFR's key takeaways.

The No Surprises Act

Surprise billing occurs when patients unintentionally receive emergency or non-emergency services from hospitals and providers who do not participate in their health plan's network.[1] Patients often bear the financial burden of such "out-of-network" or "OON" services, unless otherwise protected by state law.[2] The NSA — a bipartisan bill that was passed in the final days of 2020 as part of the omnibus Consolidated Appropriations Act, 2021 — aims to address this issue under federal law. We summarized the key features of the NSA in our Reimbursement and Payor Dispute Update published in February, 2021, but generally speaking, the NSA:

- Limits a patient's financial responsibility for OON emergency services, most non-emergency services furnished by OON providers at in-network ("INN") hospitals, and OON air ambulance services to the amount for which the patient would be responsible had those services been furnished by INN providers (i.e., INN cost-sharing amounts); and
- Requires health plans and issuers to reimburse providers and hospitals directly and resolve reimbursement disputes under a statutory independent dispute resolution ("IDR") process.

The NSA becomes effective on January 1, 2022, and comprehensively applies to all commercial health plans and issuers offering group or individual health insurance coverage (including grandfathered plans, self-funded group health plans regulated by the Employee Retirement Income Security Act of 1974 ("ERISA"), state health plans, church plans, and individual exchange, non-exchange, and student health insurance coverage). The NSA does not apply to health reimbursement arrangements, short-term limited-duration insurance, or retiree-only health plans.

Part I IFR Key Takeaways

The Part I IFR largely focuses on three key areas:

- How the amount known under the NSA as the "Qualifying Payment Amount" or "QPA" is determined, which is the amount upon which patient cost-sharing will usually be based and a factor considered in the IDR process;

[1] https://www.hhs.gov/about/news/2021/07/01/hhs-announces-rule-to-protect-consumers-from-surprise-medical-bills.html

[2] While some states have enacted laws addressing this issue in varying ways, not all states have done so, and even those states with existing law on the books are generally unable to regulate many patient encounters, including those encounters with patients who have health coverage under a self-funded health benefits plan regulated by Employee Retirement Income Security Act of 1974 ("ERISA").

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- Patient protections and details regarding how providers furnishing OON services at INN facilities may obtain a patient's informed consent to receive OON services, thereby taking those services outside of the NSA's coverage; and
- How existing state law will interact with the NSA.[3]

The Qualifying Payment Amount ("QPA")

The NSA defines the QPA as the median contracted (i.e., INN) rate for the same or similar service provided in the same geographic region, but largely leaves the details regarding this definition subject to rulemaking. Below is a brief list of several key features of the Part I IFR related to the QPA definition, and how it will be calculated.

- **The pool of contracted rates will not be provider specific.** This means that when a plan or issuer is calculating the QPA (i.e., a median "contracted rate") for a particular item or service, it will look to all "contracted rates" with any hospital or professional (as applicable) in the applicable geographic region.[4]
- **Rental network rates are "contracted rates" but single case agreements are not.** This means that the pool of "contracted rates" from which the plan or issuer will identify a median will include all rental/wrapper/leased network rate agreements but will not include rates set under single case agreements (or letters of agreement).[5]
- **Sponsors of self-funded group health plans may allow plan/claim administrators to determine the QPA using the "contracted rates" for all self-funded group health plans administered by the plan/claim administrator.** This means that a third-party plan/claim administrator is not limited to the "contracted rates" of any specific employer-sponsored health plan when calculating a QPA.[6]
- **There must be at least three "contracted rates" in a geographic region for there to be "sufficient information" to determine a median "contracted rate."** This means that if a health plan or issuer has less than three "contracted rates" for the applicable item or service in the relevant geographic region, there is not "sufficient information" to calculate a QPA and different rules apply.[7]
- **Plans and issuers must use an "eligible database" to determine a median "contracted rate" when there is insufficient information.** For items/services furnished during 2022 (or newly covered items/services in later years) and before there is "sufficient information," the plan or issuer must look to an "eligible database" to determine the median INN allowed amount for the same or similar item or service provided in the geographic region in the year before the year in which the item or service was furnished.[8]
- **The applicable "geographic region" depends on provider type and expands depending on when "sufficient information" is available.** For hospitals and professionals, the location where the items and services are furnished controls.[9] For air ambulance providers, the point-of-pickup controls. From there, the "geographic region" is tied to metropolitan statistical regions ("MSAs"), other areas within a state that exclude MSAs, and larger Census divisions depending on the location the item or service was furnished or, in the case of air ambulance services, the point-of-pickup, and depending on whether there is "sufficient information" to determine a

[3] Future rulemaking will address other issues, such as an audit process applicable to health plans and issuers to ensure compliance with the No Surprises Act ("NSA") and details regarding the Internal Dispute Resolution ("IDR") process.

[4] The Departments considered this situation in the specific context of air ambulance providers, and the fact that "hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers." But according to the Departments, "because participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider, they should not be required to pay higher cost-sharing amounts . . . solely because the air ambulance provider assigned to them has negotiated higher contracted rates in order to cover its higher costs, or because it has a different revenue model, than other types of air ambulance providers."

[5] The Departments considered the latter types of arrangements and essentially stated that they believed these agreements do not reflect "market rates under typical contract negotiations."

[6] The Departments' stated goal for this rule is twofold: (a) to reduce the burden on sponsors of self-funded group health plans to calculate their median contracted rate on a plan-by-plan basis; and (b) to have fewer instances where a self-funded group health plan sponsor lacks sufficient information to calculate a median contracted rate.

[7] For items and services furnished in 2022, "sufficient information" exists when the health plan or issuer has at least three contracted rates in effect as of January 31, 2019 (the median of which is increased by the urban consumer price index from year-to-year to calculate the 2022 qualified payment amount ("QPA")). For items and services furnished after 2022, and when the health plan or issuer does not have "sufficient information" to calculate the median contracted rate based on January 31, 2019 rates (or newly covered items and services), "sufficient information" exists when the health plan or issuer has at least three contracted rates on January 31 of the prior year and those rates accounted for at least 25% of the total number of claims paid for that item or service (the median of which is increased by the urban consumer price index from year-to-year to calculate the given year's QPA).

[8] Once the plan or issuer has determined that amount, it must increase that rate by the percentage increase in the urban consumer price index over the preceding year to arrive at the QPA. Once the plan or issuer has selected a database to use for this calculation, it cannot switch databases until the end of the calendar year unless there is a good reason to switch, such as insufficient data.

[9] If the item or service is furnished within a metropolitan statistical area ("MSA") as published by the U.S. Census Bureau, the same "geographic region" is that specific MSA. If there is not "sufficient information" within that specific MSA, the "geographic region" is all MSAs within the state. If there is not "sufficient information" within all MSAs within the state, the "geographic region" is all MSAs within the applicable Census division. If the item or service is furnished outside of an MSA, the "geographic region" is all portions of the state excluding MSAs. If there is not "sufficient information" there, the "geographic region" is all portions of the Census division excluding MSAs.

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median "contracted rate" in a particular geographic region.[10]

- **"Same or similar service" is defined at the service code level.** Plans and issuers must calculate the median "contracted rate" at the service code level, meaning Current Procedural Terminology ("CPT") code, Healthcare Common Practice Coding System ("HCPCS") code, or Diagnosis Related Group ("DRG") code, when arriving at a QPA.
- **Plan and issuers must provide written information regarding the QPA.** If the relevant patient's cost-sharing is based upon the QPA, the plan or issuer must tell the hospital or professional the QPA for each item or service.[11] If the hospital or professional so requests, the plan or issuer must also provide in writing certain other information related to the payor's QPA calculation.[12]

Other Patient Protections and Notice/ Consent Processes

- **Plans and issuers cannot "down code" or limit what constitutes an "emergency medical condition" based solely on diagnosis codes.** This means that health plans and issuers cannot not retroactively "down code" (i.e., second guess) claims for emergency services based upon final diagnosis only.[13]
- **The Departments clarified the nuances of the notice and consent procedures (applicable to some OON non-emergency services furnished at INN facilities).** An OON professional will satisfy the NSA's "notice and consent" procedures by:
  - Providing the patient with written notice in paper or electronic form, as selected by the patient, in a form and manner that meets HHS guidance; and
  - Obtaining the patient's "consent" document in a physically separate document that is not attached to or incorporated into any other document.[14]
- **Certain "Ancillary Services" are not eligible for the notice and consent process.** Most non-emergency services furnished by OON professionals at in-network facilities are eligible for the "notice and consent" process, which, if satisfied, remove those services from the NSA's applicability. However, Congress excluded certain "ancillary services" from eligibility for the notice and consent framework and authorized the Departments to expand the definition of "ancillary services" to include items and services furnished by other professional types. The Departments included within the definition of "ancillary services" the following:
  - Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology (whether provided by a physician or non-physician practitioner);
  - Items and services furnished by assistant surgeons, hospitalists, and intensivists;
  - Diagnostic services, including radiology and laboratory services; and
  - Items and services furnished by a nonparticipating professional if there is no participating professional who can furnish such item or service at such facility.[15]

State Law Application

- **The NSA will defer broadly to state surprise billing laws.** Any comprehensive state law will likely apply instead of the NSA in the context of a fully-insured plan and/ or state-regulated insurance product (and sometimes self-funded ERISA plans as discussed below) if the state law meets the NSA's so-called "floor requirements" by:
  - Prohibiting balance billing like the NSA;
  - Limiting patient cost-sharing to INN amounts; and
  - Setting forth either a process to resolve disputes over OON reimbursement, like arbitration, or a mathematical formula for determining the total OON reimbursement rate for the item or service in question.
- **State law will apply to self-funded health plans that "opt-in" to the state law.** Self-funded plans governed by ERISA that "opt-in" to state laws (if permitted by the state law)[16] will be governed by that state law inasmuch as the state law meets the NSA's minimum requirements. However, once a plan decides to opt-in to a state law for one item or service, it must do so for all items or services.
- **Air ambulance providers will be subject to the NSA only.** The Departments recognized that the Airline Deregulation Act preempts state laws, regulations, or other provisions having the force and effect of law, which relate to the price, route, or service of an air carrier. The Departments then stated that they "are not aware of any state laws that would meet the criteria to set the out-of-network rate for nonparticipating providers of air ambulance services when providing services subject to the No Surprises Act." So, the only amounts that can be deemed the "out-of-network rate" for air ambulance providers under the NSA are:
  - The amount agreed upon through open negotiations; or
  - The amount determined in the IDR process.

Conclusion

With the NSA's effective date of January 1, 2022, rapidly approaching, facilities and professionals should begin to identify ways to operationalize the NSA and identify methods to achieve fair reimbursement for OON services. For more information and questions related to the NSA or the Part I IFR, please contact the authors.

[10] If the point-of-pickup is within an MSA, the same "geographic region" is all MSAs within the state. If there is not "sufficient information" within all MSAs within the state, the "geographic region" is all MSAs within the applicable Census division. If the point-of-pickup is outside of an MSA, the "geographic region" is all portions of the state excluding MSAs. If there is not "sufficient information" there, the "geographic region" is all portions of the Census division excluding MSAs.

[11] The plan or issuer must also give a statement certifying the QPA is the amount upon which cost-sharing was based and was determined in accordance with the regulations.

[12] This other information that must be provided upon request includes: (i) whether the QPA involved non-fee-for-service rates for certain items or services, and if so, whether the QPA for those items/ services was determined using the fee schedule or the "derived amount"; (ii) which eligible database was used to determine the QPA, if any; (iii) which "related service code" was used to determine the QPA, if any; and (iv) if applicable, a statement showing whether there are any quality incentives in a payor's contracted rates, and if so, stating those quality incentives have been excluded.

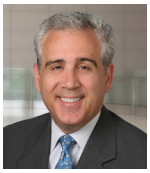
[13] The Departments definitively stated that such practices "are inconsistent with the emergency services requirements of the No Surprises Act and the ACA."

[14] CMS issued a "**Standard Notice and Consent Documents Under the No Surprises Act**" that must be used. The nonparticipating professional must satisfy the "notice and consent" criteria not later than 72 hours prior to the date on which the items or services are furnished, or on the date the patient makes the appointment for such items or services when the appointment is scheduled less than 72 hours before the items or services are to be furnished.

[15] The Departments also issued a separate rule that rendered ineligible for the "notice and consent" criteria any items or services "furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating [professional] satisfied the notice and consent criteria[.]"

[16] At the time of this writing, there are 4 states that allow plans to opt-in to their state surprise billing schemes: New Jersey, Nevada, Virginia, and Washington.

How President Biden's Executive Order Will Promote Competition in Health Care



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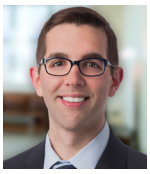

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On July 9, 2021, President Biden signed an Executive Order to reduce corporate consolidation and increase competition in the U.S. economy. A summary from the White House is available here. The order includes a government-wide effort with 72 initiatives that will be implemented by more than 12 federal agencies.

The order includes a government-wide effort with 72 initiatives that will be implemented by more than 12 federal agencies. The White House also established a Competition Council that will be led by the Director of the National Economic Council (NEC) to coordinate and monitor the federal government's implementation of the President's competition priorities. The council held its first meeting on September 10, 2021, where NEC Director Brian Deese said, "the President's competition agenda is the core to the Administration's plan to Build Back Better and critical to keeping prices low for American consumers, spurring innovation, and allowing small businesses to compete on a level playing field."

Although the order is wide-ranging across industries, it includes several of the President's top health care priorities. This includes directives on hospital and insurance transparency, addressing prescription drug prices, increasing access to hearing aids, and reforming labor rules for non-compete and occupational licensing.

Hospital Consolidation and Price Transparency

The first major priority the order seeks to address is hospital consolidation and price transparency. The President calls on the Department of Justice (DOJ) and Federal Trade Commission (FTC) to review and revise their merger guidelines and "vigorously" enforce antitrust laws while also challenging prior "bad" mergers that were not challenged by prior Administrations.

Prior to the President issuing the order, the FTC voted to approve a series of resolutions to prioritize enforcement of health care businesses such as pharmaceutical companies, pharmacy benefits managers, and hospitals. On September 15, 2021, the FTC voted to withdraw the approval of the Vertical Merger Commentary that was jointly published by the FTC and DOJ in 2020. The FTC and DOJ also issued a joint statement launching a review of merger guidelines with the goal of updating them to reflect current economic realities.

The order also directs the Department of Health and Human Services (HHS) to support existing hospital price transparency rules and to finish implementing federal legislation to address surprise medical billing. On July 1, 2021, the Biden Administration issued the first in a series of interim final rules that will implement surprise billing restrictions beginning in January 2022. On July 19, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a proposed hospital outpatient rule with several modifications to the Trump Administration's price transparency requirements, including increasing the civil monetary penalties for noncompliance.

In addition to the hospital transparency provisions, the order also directs the Department of Health and Human Services (HHS) to standardize plan options in the National Health Insurance Marketplace to streamline the federal marketplace and reverse some of the Trump Administration's changes to the Affordable Care Act (ACA). Strengthening the ACA's marketplaces has been a top priority for the Biden Administration and will continue to be a primary focus in the coming months.

Drugs and Hearing Aids

The President is also directing federal health care agencies to increases competition and lower the cost of prescription drugs and hearing aids. Building on efforts from the Trump Administration, the order calls on the Food and Drug Administration (FDA) to work with states to import prescription drugs from Canada. It also directs HHS and the FTC to ban "pay for delay" agreements and promote competition for generic and biosimilar drugs. HHS has also been tasked with issuing a comprehensive plan to combat high

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prescription drug costs.

The order also seeks to increase access to hearing aids by directing the FDA to consider issuing proposed rules within 120 days to allow hearing aids to be sold over the counter (OTC). Current law requires a hearing examination from a state licensed medical professional prior to receiving a hearing aid. In 2017, Congress passed legislation as part of the FDA Reauthorization Act directing the agency to issue new regulations establishing an OTC hearing aid market. The FDA was directed by Congress to issue the proposed rule by August 2020, but the COVID-19 pandemic delayed the agency's rulemaking plans. Although the proposed rule has been delayed for a year, the FDA sent the proposed rules to the White House Office of Management and Budget (OMB) for review on August 18, 2021.

Additionally, the Democratic majority in Congress is currently debating a budget reconciliation bill that is expected to include drug price reforms, along with a possible expansion of Medicare benefits to cover hearing, vision, and dental benefits. When Congress established Medicare in 1965, lawmakers excluded most hearing, vision, and dental benefits. The Congressional Budget Office (CBO) has estimated that expanding Medicare to cover these types of services could cost approximately $358 billion.

Under the rules of budget reconciliation, the Senate can avoid the filibuster's 60-vote threshold and pass legislation with a simple majority. Although agreement within the Democratic caucus has not yet been made on drug pricing reforms, President Biden recently expressed support for allowing Medicare to directly negotiate drug prices. The Medicare Modernization Act of 2003 established the Medicare drug benefit program and prohibited the federal government from directly negotiating drug prices. The current drug benefits in Medicare are negotiated by private insurance plans. CBO has estimated that allowing Medicare to negotiate drug prices could lower government spending by about $456 billion.

Labor & Workforce

Lastly, President Biden's order encourages the FTC to ban or limit non-compete agreements and unnecessary occupational licensing restrictions that impede economic mobility. While the order does not include a timeline for the FTC to undertake these directives, the new Chairwoman of the FTC is more supportive of federal rules targeting anti-competitive practices and has authored several papers making the case for more federal-level competition rulemaking under the Federal Trade Commission Act.

Although the President's order will not result in immediate changes to federal regulations, it outlines several health care priorities that the Biden Administration plans to pursue through regulation and legislation in the coming months to increase competition and lower health care costs.

Changes to CMS' Final Rule on Pricing Transparency Are Anything But Clear

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On July 9, 2021, President Joe Biden's administration issued an Executive Order on Promoting Competition in the American Economy, which reiterated the Government's intention to implement and enforce the Price Transparency Requirements for Hospitals to Make Standards Charges Public Final Rule ("Final Rule") initially issued on November 15, 2019. The Final Rule became effective on January 1, 2021, though several changes have already been proposed.

The Final Rule applies to all hospitals operating within the United States and primarily focuses on new requirements for hospitals to disclose how much hospital services cost, including negotiated rates with payers and minimum and maximum negotiated charges that apply to inpatient and outpatient services. CMS also outlined its expectations for how to make these price transparency websites for certain services "shoppable," such as making them digitally searchable and requiring plain language descriptions of services. Additionally, CMS promulgated standards for monitoring and enforcement of the price transparency rules, which can rise to the level of civil monetary penalties ("CMP"). The July 9, 2021 Executive Order directed HHS "to support existing hospital price transparency rules and to finish implementing bipartisan federal legislation to address surprise hospital billing," and to standardize plan options in the National Health Insurance Marketplace so people can comparison shop more easily.

Recently, CMS has also proposed changes to the Final Rule that could have large financial ramifications on hospitals found to be non-compliant with the Final Rule as explained further below.

What Must Hospitals Do to Comply With the Final Rule?

Effective January 1, 2021, hospitals are required to publicly disclose all hospital standard charges for all items and services in a comprehensive machine readable file and display shoppable services in a consumer-friendly manner. (For more details on the Final Rule's compliance requirements, see Polsinelli's November 2019 article discussing the same here.)

To promote compliance, CMS has already proposed changes to the Final Rule. Chief among these changes is a proposed increase in civil monetary penalties for non-compliant hospitals with more than 30 beds.

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Specifically, for a hospitals with bed counts between 31 and 550, the maximum daily dollar CMP amount would be the number of beds multiplied by 10. But, for hospital's with more than 550 beds, the daily CMP is capped at $5,500. A smaller hospital with 30 or fewer beds will remain unaffected by this proposed change and would be assessed a maximum CMP amount of $300 per day of non-compliance, for a total possible annual fine of up to $109,500. Larger hospitals can incur fines between $113,150 – $2,007,500 per year per hospital depending on the number of beds the hospital has.

Hospitals' Reaction to the Final Rule

The Final Rule was met with plenty of opposition from numerous businesses, professional associations, and others. Primarily, critics argue that:

- The price information that hospitals must disclose under the Final Rule is not helpful because it does not include out-of-pocket costs;
- Compliance with the Final Rule is neither feasible nor possible, as many prices are a function of complex algorithms and cannot be reasonably calculated in advance;
- The Final Rule may lead to collusion between providers;
- The cost of compliance is unduly high and vastly undercalculated by CMS. (For context, CMS estimates that, in the first year, compliance with price transparency regulations will cost $11,898.60 per hospital, and the cost will decrease to $3,610.88 per hospital in later years); and
- The Final Rule is poorly written and ambiguous.

Hospitals with more complex rate schedules will struggle to comply with the Final Rule, let alone comply in a cost-efficient manner, especially those with hospitals in multiple states, who often have thousands of agreements with payers, each with 10-15 unique benefit designs.

So How Are Hospitals Complying With the Final Rule?

A handful of reports published this year suggest that many hospitals and health systems likely do not comply with the rule. For example, a March Health Affairs analysis of the largest 100 U.S. hospitals found that 65 were "unambiguously non-compliant" by early February, with some of the remainder showing mixed levels of compliance, while a more recent analysis from Milliman found that 68% of included health systems had posted a file containing information by early March; however, the report also noted there was a "wide degree of diversity" in how the information was presented. Perhaps the most damming study has come from Patient Rights Advocate (a nonprofit organization and proponent of the Final Rule), which conducted a sample of 500 hospital websites and reported that 94.4% of hospitals had not met one or more of the Final Rule's requirements since taking effect on January 1.

Such widespread non-compliance could be attributed to the fact that many hospitals and health systems had been waiting to see whether the judiciary would halt the implementation and enforcement of the Final Rule. In particular, the American Hospital Association ("AHA"), joined by other associations, individual hospitals, and hospital systems, sued the Secretary of HHS in December 2019, arguing that the rule's interpretation of "standard charges" violates section 2718(e), the APA, and the First Amendment. But the United States District Court for the District of Columbia granted summary judgment to the Secretary on all three claims.

Further, any hope that litigation would prevail for the Final Rule's opponents seem to have been dashed in December 2020, when United States Court of Appeals for the District of Columbia Circuit denied the AHA's appeal of district court's grant of summary judgment. A motion filed by the AHA and several other organizations seeking an emergency stay of enforcement of the Final Rule was also dismissed around this time.

Is CMS Enforcing the Final Rule?

CMS began sending its first wave of warning letters to non-compliant hospitals in April 2020 and has been auditing hospitals' websites and complaint submissions since January 1. Hospitals that receive a warning letter are given 90 days to address the stated non-compliance. Thereafter, CMS may close its inquiry, deliver a second warning letter, or request a corrective action plan from the hospital, and if a hospital is still non-compliant after such action, assess a fine or CMP against the hospital.

The Final Rule specifies that facilities that receive a CMP will also be publicly named on CMS' website, though CMS has stated it has yet to reach this point with its enforcement, as prematurely releasing the names of those hospitals could harm organizations that have already updated their online pricing information or are doing so. CMS has not yet assessed any fines against a hospital that received an initial warning letter.

What Should Hospitals Do Right Now?

Recent events indicate that the Final Rule is here to stay, as it has now survived a change in presidential administrations and legal challenges. Moreover, the penalties for non-compliance are only becoming harsher and more costly. Given this outlook and CMS' early enforcement actions since the Final Rule became effective, hospitals should take steps to comply with the Final Rule and design procedures to remain compliant going forward. While many questions remain regarding the actual requirements of the Final Rule, a documented effort to meet a reasonable reading of these requirements should be helpful to reduce the likelihood of warning letters and ultimately CMPs. Therefore, hospitals may want to build into their compliance plans and operational schedules consistent reviews of their compliance with Final Rule and regularly update their standard charges for covered items and services.

HHS CARES Provider Relief Fund Updates

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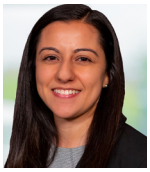

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Reporting Deadlines

Over the summer the U.S. Department of Health & Human Services (HHS) released its highly anticipated Provider Relief Fund (PRF) reporting guidance on June 11, 2021, outlining deadlines for providers to use or lose their remaining PRFs and when they will be required to report on uses as of the stated deadlines. As indicated in the table below which summarizes the deadlines for recipients based on the date of receipt of PRFs (furnished by HHS) recipients are expected to use any PRFs within approximately one year of receipt. HHS indicates through FAQs that where recipients received PRFs that fall within differing Periods those recipients must use and report on the use of such funds by the stated deadline according to the relevant Period and may not lump PRFs together into one Period and accelerate or decelerate use or reporting.

HHS Reporting Requirement Deadlines

At present, while there are no proposals to extend any of these deadlines, the first of which (Period 1) had a use deadline by June 30, 2021 and a reporting deadline of September 30, 2021, HHS did announce that it was offering a 60 day grace period (October 1 – November 30, 2021) for Reporting Time Period 1. While HHS indicates this is not a formal extension, HHS is allowing recipients impacted by recent COVID-19 surges and natural disasters around the country an additional 60 days beyond September 30, 2021, to come into compliance with their PRF reporting obligations. HHS indicates that while failing to meet the September 30 deadline puts recipients out of compliance with PRF reporting requirements, HHS will not pursue any recoupment or other enforcement actions during this 60-day grace period. Any unused funds must still be returned within 30 days of the last reporting deadline for the relevant period, and under the grace period that deadline is also extended by 60 days until December 30, 2021.

In previous PRF Reporting guidance, HHS outlined two reporting periods and required the funding be used by the second reporting date, which was June 30, 2021. This shift will help ensure recipients can adequately use the funding received towards the end of 2020 and into early and mid-2021 for COVID-related expenditures.

Overall, the categories of information recipients are required to report on remain largely the same with a few added sections of requested information built in. These added sections are the Subsidiary Questionnaire and a Survey regarding the impact of the payments. One important note regarding the reporting guidance is that HHS clarified reporting was applicable to funding received from the Skilled Nursing Facility and Nursing Home Infection Control Distribution. Those entities will have additional information to report on, which are also outlined within the new guidance.

HRSA hosted multiple webinars for recipients required to report on PRFs to HHS and has made recordings of those webinars available here. HRSA also continues to update its guidance through FAQs, the most recent of which were released on August 30, 2021 and can be found here.

Additional Funding Opportunities

Until Friday September 10, 2021, it was unclear whether or when any additional PRFs or other pandemic related funding would be made available to providers and then on that date the Biden Administration announced it was releasing an additional $25.5 billion in PRFs: $17 billion of which will be released through a Phase 4 General Distribution and an additional $8.5 billion of which will be released through the American Rescue Plan Rural (ARP Rural Distribution) (details on

HHS Reporting Requirement Deadlines

	Period 1	Period 2	Period 3	Period 4
Payment Received Period (Payments Exceeding $10,000 in Aggregate Received)	April 10, 2020 to June 30, 2020	July 1, 2020 to December 31, 2020	January 1, 2021 to June 30, 2021	July 1, 2021 to December 31, 2021
Deadline to Use Funds	June 30, 2021	December 31, 2021	June 30, 2022	December, 2022
Reporting Time Period	July 1, 2021 to September 30, 2021	January 1, 2022 to March 31, 2022	July 1, 2022 to September 30, 2022	January 1, 2023 to March 31, 2023

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the new funding can be found here). Before then, the federal government and HHS had released approximately $118 billion in PRFs, and various sources (including HHS/HRSA and the GAO) indicated between $32.5 billion and $43 billion in available funding remained with questions regarding whether those funds would be used for PRF purposes or for other competing federal priorities, such as the Administration's infrastructure proposal.

HHS indicates the Phase 4 General Distribution payments will be based on providers' lost revenues and increased expenditures between July 1, 2020 and March 31, 2021. HHS also indicates the Phase 4 PRFs will include new elements specifically focused on equity, including reimbursing smaller providers for their lost revenues and COVID-19 expenses at a higher rate compared to larger providers, and bonus payments based on the amount of services providers furnish to Medicaid, Children's Health Insurance Program (CHIP), and Medicare patients with 75% of the Phase 4 allocation based on revenue losses and COVID-related expenses, and the remaining 25% reserved for 'bonus payments' based on the amount and type of services provided to Medicaid, CHIP, and Medicare patients.

The ARP Rural Distribution will be for providers who serve Medicaid, CHIP, and Medicare patients who live in rural communities and will be based on the amount and type of services provided to rural patients.

In recognition of Congress's recent concerns regarding whether prior PRFs were used to fund recent merger and acquisition activity, HHS emphasizes that the Phase 4 PRFs are to be used for patient care, and that recipients of the new Phase 4 PRFs will be required to notify the HHS Secretary of any merger with or acquisition of another healthcare provider during their Payment Received Period. HHS further indicates that providers who report a merger or acquisition during such Period may be more likely to be audited to confirm their funds were used for COVID-related costs, consistent with an overall risk-based audit strategy.

The application portal for Phase 4 PRFs opened on September 29, 2021.

Behavioral Health — Provider Considerations for the Evolution to Value-Based Care — Part II

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Earlier this year, we explored the enormous potential for payors, providers, and patients of shifting from volume-based, fee-for-service reimbursement models for behavioral health care to value-based reimbursement models. Here we balance that potential by examining some of the risks providers should consider as the market shifts to value-based behavioral health care.

The most tangible benefit of value-based reimbursement models from the payor perspective is more predictability. Value-based reimbursement refers to health care delivery and payment models in which providers, payors and patients are all incentivized to promote delivery of appropriate, high-quality and cost-effective care. Today, value-based arrangements range from simple payfor-performance models, to more sophisticated "population health" or "episodes of care" arrangements involving shared savings and shared financial risk — all of which are linked to evolving measures of quality.

After finding success on these fronts with value-based reimbursement models in the medical world, some payors are now looking to implement similar reimbursement programs to help provide predictability to their behavioral health spend while maintaining or improving quality of care. While value-based reimbursement models can offer many benefits for behavioral health providers, including increased flexibility to determine appropriate care (including the appropriate level of care), higher patient satisfaction, and potential for increased aggregate reimbursement, behavioral health providers should maintain only cautious optimism about such models.

It seems like only a few years ago that much of behavioral health care was provided on a cash-only basis. For many payors, behavioral health care is still considered a new coverage benefit — one that they are still learning how to manage and to pay for. The frustrating reality of this learning curve has led to fee-for-service payment models that payors view as too costly and that providers view as too rigid and out of alignment with clinically driven, evidence-based care models. The shift to value-based reimbursement models, however, could expose behavioral health providers to unintended risks. We outline some of the potential risk areas unique to value-based reimbursement models for behavioral health providers.

Challenges With Data

Provider performance under every value-based reimbursement model is scored based on agreed upon objective metrics measuring success. The precise metrics can vary widely, from financial metrics on total cost of care to performance metrics measuring provider services furnished to quality metrics on patient clinical outcomes. However, what is common to all metrics in every value-based reimbursement model is that reliable data is needed to measure success and that the parties agree to the data points and sources relevant to the defined model.

For many reasons, reliable data is not always available, and it is not always clear what data points are important. Perhaps the behavioral health provider doesn't track the reasons why a patient missed a therapy session. Perhaps the payor's claims systems can't track whether a patient's emergency department visit was due to a relapse or some other emergency. Perhaps a payor is so new to the behavioral health space so it is reluctant

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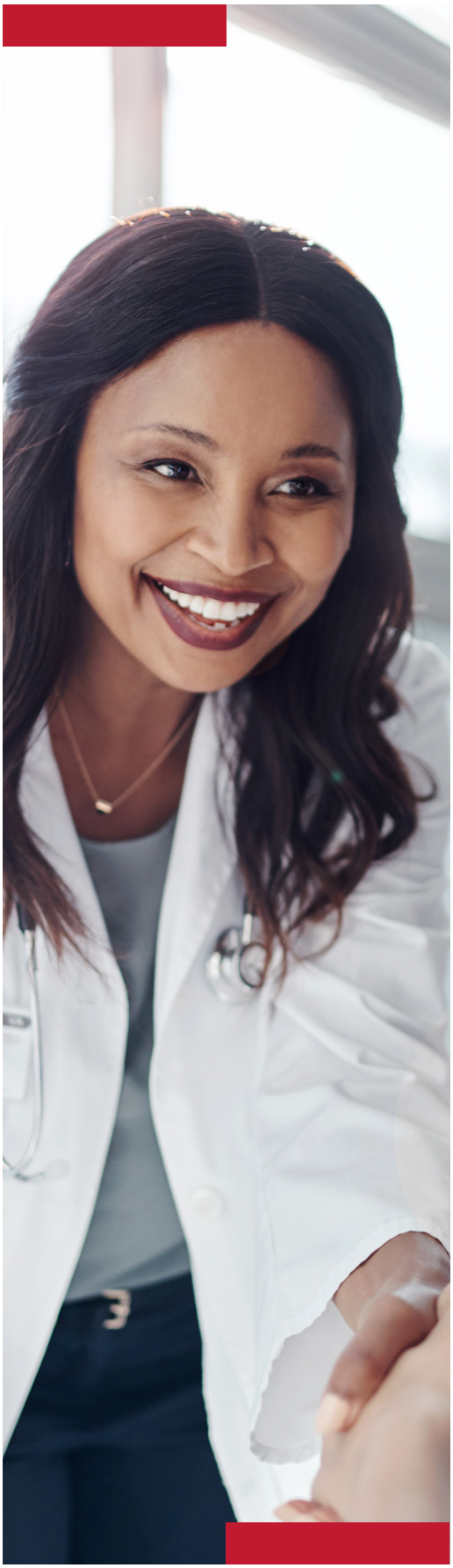

to consider shared savings arrangements until it can better predict its baseline costs. Perhaps the payor has spent a lot of resources internally developing a value-based model it want to roll out to its contracted providers, but the data assumptions it uses do not align with the provider's view of quality and efficacy of treatment.

Whatever the reason, challenges with data narrow the types of value-based reimbursement models reasonably available to a particular behavioral health provider and a particular payor. Early conversations between payors and behavioral health providers are often needed to identify the relevant data points and to begin gathering necessary data on which to build a successful value-based partnership. While these early conversations can present an opportunity for behavioral health providers to help payors develop value-based reimbursement models that align with their care models, they should also cause behavioral health providers to consider whether they have the capabilities to track the data necessary to prove success under the proposed model, even if they do not necessarily agree with the payor on the relevance of such data. Sometimes the answer will be "no."

Poorly Defined Models

Even when data is available, behavioral health value-based reimbursement models are often new and untested. That combination means that unforeseen complications may not have been sufficiently accounted for in the model. We have seen models that fail to address how lab testing will be accounted for, who gets to decide when it is appropriate to step-down care, and what kinds of post-discharge health care needs should be the behavioral health care providers' responsibility.

This lack of definition in the value-based reimbursement model can present significant risk to the behavioral health provider. In these circumstances, the payor will likely take the position that the payor has the sole discretion to make decisions on all undefined issues, often in hindsight. It is also reasonable to assume that the payor will act opportunistically to make decisions that benefit the payor financially, at the behavioral health providers' expense.

Contractually, behavioral health providers should ensure that all foreseeable complications are addressed in the contract documents. Characteristics like performance metrics, metric measurement criteria, inclusions and exclusions, payment calculations and timing, and documentation obligations need to be well-defined. Proper alignment on these details in advance is key to success for all parties involved in value-base care. While the provider does not always have significant leverage to insist on contractual terms with payors, failure to align on these details in advance can present significant risk to the behavioral health care provider.

Challenges Adjusting to Value-Based Care

Value-based reimbursement is coming to behavioral health care and few behavioral health providers are ready to participate. That's okay (payors are not necessarily ready either)! Achieving consistent clinical success is hard enough when financial success isn't tied to patient outcomes. But one of the goals of value-based care is to incentivize innovation and changes. That might mean reconsidering clinical programming, oversight, and operational practices that, for some behavioral health providers, have been in place for decades.

For some, the changes needed to be successful in value-based reimbursement models will be significant. It might mean providing disease prevention, care management, or post-discharge patient tracking for the first time. It might mean offering innovative therapies and assessing their effectiveness or contracting with community medical providers to tackle co-occurring conditions impacting behavioral health. It might mean hiring data analysts to better understand the patient population. Whatever changes are needed will take time to implement, time to perfect, time to gather data supporting clinical success, and time to negotiate appropriate value-based reimbursement models with different payors.

Today is the day to start assessing program readiness for value-based care and talking to your health care payors because tomorrow it will be here.

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Contact Sinead McGuire, smcguire@polsinelli.com, for more information about any upcoming Polsinelli Health Care events.

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