ROPES & GRAY

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HOSPITAL AND HEALTH SYSTEM QUARTERLY REIMBURSEMENT CHECK

EACH QUARTER, ROPES & GRAY ATTORNEYS share their analysis of administrative and court litigation, regulatory developments, and other key developments affecting federal program payments to hospitals and health systems. Below are the takeaways from this quarter's review.

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FOCUS ON

CMS'S EVOLVING APPROACH TO TREATMENT OF SECTION 1115 WAIVER DAYS IN MEDICARE DSH CALCULATION

For more than two decades, the Medicare dispropor-tionate share hospital ("DSH") regulation has permitted hospitals to include days in the numerator of the Medicaid fraction that are attributable to patients who were covered under a Centers for Medicare & Medicaid Services ("CMS")-approved Section 1115 waiver. But in spite of its regulation, CMS for years has attempted to exclude from the DSH calculation days of patients covered under Section 1115 waivers through an uncompensated care pool program or premium assistance program. After losing before multiple courts in cases relating to waiver programs in three different states, CMS finally appears poised to permit hospitals to claim these categories of waiver days as Medicaid days in the DSH calculation. As discussed below, this presents an opportunity for hospitals located in states with these kinds of Section 1115 waiver programs to increase their Medicare DSH reimbursement.

For years, the CMS and its contractors have attempted to exclude days from the numerator of the DSH Medicaid fraction attributable to patients who were covered under a CMS-approved Section 1115 waiver. Section 1115 of the Social Security Act ("Act") permits CMS to waive Medicaid requirements to permit "experimental, pilot, or demonstration project[s]" that are "likely to assist in promoting the objectives" of Title XIX of the Act. 42 U.S.C. § 1315(a). Under the controlling regulation initially adopted in 2000 and amended in 2003, "hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act" so long as the patient is "eligible for inpatient hospital services" under the waiver. 42 C.F.R. § 412.106(b)(4)(i)-(ii).

Since 2018, federal courts have repeatedly overturned CMS's disallowance of waiver days under CMS-approved Section 1115 demonstration projects. In the first case, *HealthAlliance Hospitals, Inc. v. Azar*, the D.C. District Court held that "the plain language of the applicable regulation unambiguously requires" that patient days under Massachusetts' Commonwealth Care Health Insurance Program must be counted in the numerator of the DSH Medicaid fraction. 346 F. Supp. 3d 43, 56, 60 (D.D.C. 2018). A year later, in *Forrest General Hospital v. Azar*, the Fifth Circuit similarly concluded that patient days funded through Mississippi's uncompensated care pool must be included in the numerator of the Medicaid fraction. 926 F.3d 221, 226, 234 (5th Cir. 2019). Most recently, in *Bethesda Health, Inc. v. Azar*, the D.C. Circuit found that the patient days under Florida's Low Income Pool could be included in the plaintiff hospitals' Medicaid fractions. 980 F.3d 121, 122-23 (D.C. Cir. 2020).

In light of these court decisions, CMS has twice proposed to amend the regulation to limit the inclusion of Section 1115 waiver days in the Medicaid fraction on a prospective basis. *See* 86 Fed. Reg. 25,070, 25,457-59 (May 10, 2021); 87 Fed. Reg. 28,108, 28,400-01 (May 10, 2022). But CMS did not finalize its proposal either time. *See* 86 Fed. Reg. 44,774, 45,249 (Aug. 13, 2021); 87 Fed. Reg. 48,780, 49,051 (Aug. 10, 2022). This leaves CMS's existing rule permitting the inclusion of waiver days in the DSH calculation in place, although the agency may revisit the rule again in a future rulemaking.

In light of the three adverse court decisions discussed above, CMS appears to be poised to allow hospitals to claim Section 1115 waiver days in the Medicare DSH calculation. In an instruction issued in May 2022, CMS informed its Medicare Administrative Contractors they must accept amended cost report filings when "the provider is seeking to amend their cost report to include Section 1115 Waiver days for DSH reimbursement purposes." TDL 220374 (May 6, 2022). This means that hospitals located in states with Section 1115 programs covering uncompensated care pools and premium assistance programs that CMS has historically disallowed can now go back and file amended cost reports for any open cost years (i.e., any cost years that have not received NPRs) and request their MACs to include Section 1115 waiver days in the DSH calculation. The MACs have been instructed to accept such amended cost reports and to issue tentative settlements or NPRs to providers that include waiver days in the DSH calculation. We understand that MACs have also been granting reopening requests for cost reports that are within the 180-day window for filing an appeal. While the instruction provides for the inclusion of waiver days in the DSH calculation, it also provides for the MACs to go back and reopen cost years that are later determined to have erroneously claimed days. While CMS has left the MACs with the ability to reopen cost reports that are settled including waiver days, CMS's instruction presents an opportunity for hospitals located in states with Section 1115 waivers to get additional cash in the door, at least for any cost years that have not been settled.

What have our lawyers been up to?

- Health care partner **BRETT FRIEDMAN** rejoined Ropes & Gray after serving as Deputy Commissioner at the New York State Department of Health (NYSDOH) and as the State Medicaid Director. Read our full alert.
- On October 16, 2022, partner **BEN WILSON** led an engaging roundtable discussion on Population Health Strategies for Addressing Social Care Needs and Advancing Health Equity at Consero's Healthcare General Counsel Forum. Discussion focused on a number of novel initiatives being pursued by academic medical centers and health systems to advance health equity and address social care needs; value-based care arrangements and other funding opportunities for such initiatives; and the legal and practical issues faced by institutions partnering with community-based organizations.

We expect continued developments in this area of Section 1115 waiver days and recommend that hospitals evaluate whether they are located in states with Section 1115 waivers covering inpatient hospital services and, if so, if those days should be included in the DSH calculation. In addition, we recommend that hospitals continue to appeal the Section 1115 waiver days issue from any NPRs that exclude those days, even if the hospital has otherwise requested a reopening but has not yet received a revised NPR including the hospital's waiver days.

DOCKET UPDATES

1. SUPREME COURT UPHOLDS AGENCY'S INTERPRETATION OF DUAL ELIGIBLE MEDICARE PART A EXHAUSTED BENEFIT (NON-COVERED) DAYS IN THE MEDICARE DSH CALCULATION

On June 24, 2022, in a 5-4 decision, the Supreme Court "approve[d]" the agency's new interpretation of "entitled to benefits under [Medicare] part A" as applied to the counting of inpatient hospital days for "patients whom Medicare insures but does not pay for on a given day" in the Medicare DSH payment calculation. *Becerra v. Empire Health Found.*, 142 S.Ct. 2354, 2358, 2361 (2022). The dissent, written by Justice Kavanaugh and joined by Chief Justice Roberts as well as Justices Alito and Gorsuch, concluded that the agency did not have the "best reading" of the statute. The dissent explained that under a "straightforward and commonsensical" reading, patients are "entitled to have payment made by Medicare for particular days in the hospital if Medicare was obligated to pay for the patient's care for those days."

After the Supreme Court's decision, the plaintiff hospital requested that the Ninth Circuit address an alternative argument, which it had previously raised but neither the Supreme Court nor the Ninth Circuit had reached, that the agency's interpretation of "entitled to [SSI] benefits" is improperly narrower than its interpretation of "entitled to benefits under [Medicare] part A." The government opposed the hospital's request and asked the Ninth Circuit to affirm the District Court's dismissal for lack of jurisdiction on this claim or otherwise rule against the hospital on the merits. The Ninth Circuit has not yet ruled on the hospital's request.

2. SUPREME COURT OVERTURNS REDUCTION IN REIMBURSEMENT FOR OUTPATIENT DRUGS PURCHASED BY HOSPITALS UNDER 340B PROGRAM

On June 15, 2022, a unanimous U.S. Supreme Court decided in favor of the American Hospital Association ("AHA") in its challenge to the 2018 and 2019 final rules reducing the amount of reimbursement for outpatient prescription drugs provided by hospitals participating in the 340B Drug Pricing Program ("340B Program"). The court held that HHS's rules reducing reimbursement for drugs purchased through the 340B Program were inconsistent with the Medicare Act. Our prior alert summarizes the key portions of the court's decision and discusses the implications of the decision.

Read a recent Ropes & Gray alert to learn more about this case.

3. D.C. CIRCUIT HOLDS THAT 2016 RULE DEFINING CLINICAL LABORATORIES IS ARBITRARY AND CAPRICIOUS

On July 15, 2022, the D.C. Circuit issued its decision in *American Clinical Laboratory Association v. Becerra*, finding that the agency's 2016 rule defining what constitutes "applicable laboratories" for the purpose of setting Medicare reimbursement rates under the Protecting Access to Medicare Act of 2014 ("PAMA") is arbitrary and capricious. The agency's 2016 rule defined "applicable laboratories" to include only those laboratories with separate NPI numbers, which effectively excluded all hospital-based laboratories, as they generally submit claims through the hospital's NPI. The plaintiff argued that by excluding hospital-based laboratories from the private market data used to determine the Medicare rates under

PAMA, the agency unlawfully decreased the Medicare reimbursement rates for all clinical laboratories. The D.C. Circuit held the 2016 rule was arbitrary and capricious under the APA because "the agency, without adequate explanation, exempted a sizable portion of the laboratories covered by the statute from data reporting requirements." 40 F.4th 616, 625 (D.C. Cir. 2022). The D.C. Circuit also held that the agency's issuance of a new 2018 rule expanding the definition of "applicable laboratories" did not moot plaintiff's challenge to the 2016 rule because the agency only "temporarily alter[ed]" its 2016 policy and did not demonstrate that "there is no reasonable expectation that' the agency [would] restore" that policy. *Id*. at 622-23. With respect to remedy, the D.C. Circuit ordered the District Court to enter declaratory judgment in plaintiff's favor but rejected plaintiff's request to vacate the 2016 rule, given that the agency had already replaced it with the 2018 rule.

4. D.C. DISTRICT COURT FINDS AGENCY'S INTERPRETATION OF "ENTITLED TO [SSI] BENEFITS" PERMISSIBLE

On June 8, 2022, the D.C. District Court issued an unfavorable decision for the plaintiff hospitals in *Advocate Christ Medical Center v. Azar*, which the hospitals subsequently appealed to the D.C. Circuit. No. 17-cv-1519 (TSC), 2022 WL 2064830, (D.D.C. June 8, 2022), *appeal docketed*, No. 22-5214 (D.C. Cir. Aug. 12, 2022). The hospitals argued that the agency's interpretation of "entitled to [SSI] benefits" in the SSI fraction is unlawful because it differs from the agency's interpretation of "entitled to benefits under [Medicare] part A" as used in the same sentence of the DSH statute. They also sought a writ of mandamus compelling the agency to provide them with the Social Security Administration's payment status codes for all persons enrolled in the SSI program so that they could verify and challenge CMS's calculation of their DSH adjustments. The court denied both claims. First, applying the traditional *Chevron* analysis, the court concluded that the agency "adequately explained that the perceived inconsistency arises from the two distinct types of statutory entitlements at issue—SSI cash benefits versus Part A insurance benefits." *Id*. at *8. Second, as to the mandamus claim, the court held that the hospitals failed to show that they had a clear right to relief or that the agency had a clear duty to act. Briefing at the D.C. Circuit is scheduled to begin in November.

REGULATORY UPDATES

1. CMS RELEASES FINAL HOSPITAL INPATIENT PAYMENT RULE FOR FEDERAL FISCAL YEAR 2023

On August 1, 2022, CMS released the final rule for the federal fiscal year ("FY") 2023 inpatient prospective payment system ("IPPS") and long-term care hospital ("LTCH") payment system, which was published in the Federal Register on August 10, 2022. In April 2022, just after the publication of the IPPS proposed rule, we circulated an alert summarizing certain aspects of CMS's proposals. Following publication of the final rule, we circulated a further alert summarizing what CMS determined regarding each of the following topics in the final rule: A. COVID-19-Related Payment Calculation and Reporting Changes; B. Performance and Data Reporting Requirements; C. Medical Education Payments; D. Disproportionate Share Hospital Payments; E. Wage Index and Geographic Reclassification; and F. the Medicare Interoperability Program. As discussed in our alert, CMS decided to finalize a majority of its proposals in this final rule, but notably did not finalize its proposed limitation on counting Section 1115 waiver days in the Medicare DSH calculation.

Read Ropes & Gray's alert for our analysis of the Final Rule, and further details regarding Section 1115 waiver days in the DSH calculation can be found in our Focus On article on page 1 above.

2. CMS PUBLISHES CY 2023 HOSPITAL OUTPATIENT PAYMENT PROPOSED RULE AND ADDRESSES 340B DRUG PAYMENTS, ORGAN ACQUISITION COSTS, PANDEMIC-RELATED PAYMENT CHANGES, RURAL HOSPITALS

On July 26, 2022, CMS published in the Federal Register its annual proposed rule for the calendar year ("CY") 2023 outpatient prospective ("OPPS") and ambulatory surgical center ("ASC") payment systems. Our prior alert detailed key changes proposed by CMS on the following topics: A. Payment for 340B Drugs; B. Reimbursement for Organ Acquisition Costs; C. Changes Relating to COVID-19 Pandemic, Including Updates to the Conversion Factor, Claims Data Used for Rate-Setting, a Payment Adjustment for the Purchase of Approved Surgical N95 Respirators, and Mental Health Telehealth Services; D. Use of Information Related to Hospital Transactions; and E. Policies for a New Category of Rural Hospitals. We expect the final rule to be published in November.

Read Ropes & Gray's alert for our analysis of the Proposed Rule

3. MASSHEALTH 1115 WAIVER EXTENSION AND POTENTIAL IMPACT ON OTHER STATES

On September 28, 2022, CMS approved Massachusetts' request to extend the Medicaid program demonstration entitled "MassHealth" (Project Number 11-W-00030/1 and 21-W00071/1) in accordance with section 1115(a) of the Social Security Act (the "1115 waiver"). In addition to extending existing demonstration programs, such as Massachusetts' innovative accountable care organization ("ACO") approach for population health management, the 1115 Waiver amendment is significant, as it approves new programs—and thus billions of dollars in new federal Medicaid funding—to test the efficacy of interventions that aim to improve health equity for vulnerable populations. These programs include the expansion of Medicaid coverage to a limited subset of new groups and the addition of new covered services, including interventions that address health-related social needs ("HRSN"). While many of the implementation details, quality measures and specific funding mechanisms still need to be hammered out in the coming months, CMS's approval represents an exciting development that will benefit hospitals, ACOs, community-based organizations that address HRSN, and health services companies that help achieve these goals.

Approval of this waiver by CMS is a significant development for health systems, health plans and investors in markets outside of Massachusetts, as it conveys a willingness by CMS to once again use its broad 1115 waiver authority to make new federal investments that support safety net and financially distressed hospitals, especially for health systems that operate in underserved, high-Medicaid areas, and expand Medicaid coverage to both new populations and new service offerings, such as HSRN and behavioral health. This waiver also likely serves as a strong indication that pending 1115 waiver amendments, including New York's waiver submitted in September 2022, will receive similar approvals from CMS in the near future and collectively represent an exciting new opportunity for healthcare innovation and the development of new care models.

Read Ropes & Gray's alert for our full analysis of this 1115 waiver.

4. HOW ENACTMENT OF THE INFLATION REDUCTION ACT PAVES THE WAY FOR DRUG PRICING REFORMS

In a *Law360* article co-authored by heath care partner Margaux Hall and health care associates Emma Coreno, Nick Curry and Scott Falin, the authors examine how the Inflation Reduction Act ("IRA"), which was signed into law by President Joe Biden in mid-August, paves the way for major drug pricing reforms that may have impacts on hospital reimbursement.

Most notably, the new law establishes a program empowering Medicare for the first time to directly negotiate prices with manufacturers for certain high-spend drugs, requires manufacturers to pay rebates to Medicare for drugs reimbursed under Parts B and D with price increases that exceed inflation, and revamps the Medicare Part D prescription drug benefit to provide greater cost-sharing protections for beneficiaries and alter existing obligations for plans and manufacturers.

While it will be years before the IRA is fully implemented—and even longer before many of its effects are fully realized—the law is the most significant drug pricing legislation in recent memory and will have significant implications for the life sciences and healthcare sectors. For example, the government negotiation provisions in the IRA will result in selected Part B products being reimbursed at 106 percent of the specified "maximum fair price." The "maximum fair price" is expected to be lower than ASP and, consequently, hospitals and other providers may confront lowered reimbursement on physician-administered drug products.

Read the full *Law360* article.

ENFORCEMENT UPDATES

1. HHS OIG AND HHS HRSA CONDUCTING AUDITS OF PROVIDER RELIEF FUND RECIPIENTS

The Health Resources & Services Administration ("HRSA") Provider Relief Fund ("PRF") Terms and Conditions, as well as applicable laws, generally authorize the U.S. Department of Health and Human Services ("HHS") to audit PRF payment recipients to ensure compliance with program requirements.

The HHS Office of Inspector General ("OIG") indicated in its work plan that it will perform a series of audits to determine whether PRF payments—including General Distribution and Targeted Distribution payments—were (i) correctly calculated for providers that applied for these payments, (ii) supported by appropriate and reasonable documentation, (iii) made to only eligible providers, and (iv) made to providers that have complied with the terms and conditions for expending and reporting on the use of PRF funds. Providers have begun to receive these HHS OIG audits and, in practice, we have observed that these audits have focused specifically on providers' compliance with the terms and conditions for expending and reporting on the use of PRF funds, with most requests directed toward understanding how providers tracked compliance with the terms and conditions and used the PRF funds to reimburse expenses and lost revenues attributable to COVID-19.

Separately from HHS OIG, HRSA is also conducting "post-payment quality reviews" and audits of PRF recipients. HRSA's audits also appear to focus on how a provider's PRF funds were expended to reimburse it for expenses and lost revenues attributable to COVID-19, while the post-payment quality review processes are reviewing the underlying application materials for any potential discrepancies.

2. DOJ ANNOUNCES COVID-19 FRAUD STRIKE FORCE TEAMS

In May 2021, the U.S. Department of Justice ("DOJ") established the COVID-19 Fraud Enforcement Task Force in partnership with other federal government agencies to prevent, investigate and prosecute COVID-19 pandemic-related fraud, including cases and investigations involving the Small Business Administration ("SBA") Paycheck Protection Program ("PPP"), Economic Injury Disaster Loan ("EIDL") program and other COVID-19 relief programs. On September 14, DOJ also announced the establishment of three Strike Force teams operating out of U.S. Attorney's Offices in the Southern District of Florida, the District of Maryland, and a joint effort between the Central and Eastern Districts of California to enhance the COVID-19 Fraud Enforcement Task Force's work.

Since the start of the pandemic, DOJ has charged over 1,500 defendants with crimes and conducted civil investigations into more than 1,800 individuals and entities for alleged misconduct in connection with COVID-19 relief fund and healthcare fraud. Enforcement has focused on the SBA PPP and EIDL programs, including the September 22 announcement of the first PPP False Claims Act settlement in which DOJ intervened against the borrower. DOJ, however, included the HRSA PRF program in a list of programs susceptible to fraud in its September 2022 Audit of the Management and Coordination of Pandemic-Related Fraud Allegations and Referrals Between the Criminal Division and Executive Office for U.S. Attorneys.

3. OIG AUDIT REPORT FINDS THAT HRSA MISCALCULATED AND MISHANDLED DISTRIBUTIONS

Most recently, HHS OIG released an audit report on September 29, 2022, reviewing $48 billion in Phase 1 General Distribution payments that were disbursed to 323,498 providers from April 10 to December 17, 2020. HHS OIG found that there were certain procedures that were not included in HRSA's protocols that resulted in miscalculations and outstanding amounts owed to HRSA. Notably, the HHS OIG report found the following:

1. HRSA did not request and review supporting documentation from applicant providers to verify estimated revenue losses, which could have led to overpayments or underpayments. In response, HRSA will conduct manual reviews of 189 providers that received Phase 1 General Distribution funds above $2 million during Tranche 2 of Phase 1 to verify revenue losses included in application materials. HRSA will then conduct a feasibility study to determine if further manual reviews will be required.

2. HRSA did not have procedures in place to subtract the automatic payments made under Tranche 1 of Phase 1 and a portion of Tranche 2 of Phase 1 to providers' subsidiary organizations when non-automatic payments under Tranche 2 of Phase 1 were calculated. HRSA has begun to determine the impact of the overpayments through the established post-payment quality review process, including seeking repayments for any overpayments identified.

3. HRSA did not provide guidance related to returning rejected payments until August 10, 2020, when it updated its PRF FAQ document, instructing providers to return payments within 15 calendar days of rejecting them. As a result, 118 providers have not returned their rejected payments, totaling $49.9 million in outstanding payments. In response, HRSA will send rejected but not returned payments to the HHS Program Support Center for collection of any outstanding amounts owed. Of note, it is unclear from the report whether HRSA will collect rejected payments that were kept and reported on by providers.

4. HRSA has verified the reported revenue of only 2% of providers because it only reviewed providers that could potentially receive payments above $2 million for certain waves of Tranche 2 of Phase 1 and $1 million for a certain wave of Tranche 2 of Phase 1. In response, HRSA will conduct a cost-benefit analysis for manually reviewing additional providers and will assess adding a new discrepancy to its post-payment quality control review process to include manual review of Phase 1 providers meeting the above criteria.

5. Although HRSA developed a procedure to prevent providers that file federal income tax returns covering multiple legal entities from being overpaid, there was an error in the extraction of subsidiary TINs that resulted in the incorrect TIN being used in the calculations for Tranche 1 of Phase 1. In response, HRSA has begun to resolve the issue through the established post-payment quality review process but noted that this could have impacted the amount of payments in future distributions.

VALUE-BASED CARE CORNER

1. NEW CMMI MODEL INVITES PHYSICIAN PRACTICES, PAYERS TO RECONSIDER TRADITIONAL REIMBURSEMENT FOR ONCOLOGY SERVICES

On June 27, 2022, the Center for Medicare and Medicaid Innovation ("CMMI") at the CMS announced the Enhancing Oncology Model ("EOM"), a new, voluntary advanced payment model aimed at improving cancer care for Medicare patients and lowering healthcare costs. EOM is the successor to the Oncology Care Model ("OCM") and seeks to build upon the lessons learned and feedback received during its six-year run that concluded on June 30, 2022. EOM will commence on July 1, 2023 and continue until June 30, 2028. Applications to participate in EOM were due on September 30, 2022.

Unlike many of the CMMI specialty care payment models, EOM contemplates direct participation by physician practices without the use of an intermediary entity, but still offers unique opportunities to management services companies and commercial payors. Our prior alert outlined the key features of EOM and opportunities across potential stakeholders in the EOM program.

Read Ropes & Gray's alert for our analysis of the new model.

2. CHANGES TO VARIOUS ACO MODELS FROM CMS

On July 7, 2022, through the proposed Physician Fee Schedule rule, CMS announced its first significant changes to the Medicare Shared Savings Program ("MSSP") since the Pathways to Success rules. Notably, the changes include allowing ACOs to extend the period for which they are not required to take on downside financial risk. The proposed rule also would allow new ACOs to receive advanced shared savings payments from CMS, similar to the payments offered in the expired ACO Investment Model. Additionally, the changes revise the program's financial benchmarking methodology to account for value an ACO has driven through its historical participation. CMS expects to issue the final rule later this year.

At CMMI, the ACO REACH model is set to begin January 1, 2023. CMMI continues to develop the health equity benchmark adjustment and has yet to finalize the methodology for identifying and stratifying underserved beneficiaries. Meanwhile, accepted ACOs are preparing for participation and expect to receive their financial benchmarks and alignment lists later this year.

COVID-19 RELIEF FUNDING UPDATES

1. UPDATED PROVIDER RELIEF FUND FAQS

On June 30 and July 28, HRSA updated its FAQs related to the PRF to add new FAQs and modify previously released FAQs. These updates included the following:

a. **PRF Eligibility.** A provider must be in compliance with the Terms and Conditions for any previously received PRF payment to be eligible for a PRF payment.

b. **Keeping "Rejected" Funds.** A provider that initially "rejected" one or more PRF payments (>$10,000 in aggregate) but later kept the funds must report on those funds. To do so, the provider must contact the Provider Support Line to change their attestation from "rejected" to "accepted." Once the attestation has been updated, the reporting portal will be updated to reflect the kept payment.

c. **Payment Reconsiderations.** If a provider believes its PRF Phase 4 General Distribution or American Rescue Plan ("ARP") Rural Payment was calculated incorrectly, it should submit a completed PRF Reconsideration Request Form. All Phase 4/ARP Rural applicants have 45 days from the date of their Phase 4/ARP Rural payment determination notification to submit a reconsideration request. HRSA will not make changes that require a revision/correction to the application or a change to payment methodology or policy.

2. ADDITIONAL PROVIDER RELIEF FUND UPDATES

During this quarter, HRSA updated its website to show it distributed at least an additional $1.1 billion in PRF Phase 4 payments to approximately 1,000 providers. This brings the total distributed funds to approximately $15.4 billion, with an additional $1.6 billion still left in the Phase 4 distribution.

Additionally, HRSA updated its website with clarifica-tions regarding PRF reporting requirements and plans to set up a dispute and appeal process for PRF recipients whose funds are being recouped by HRSA. These updates are summarized below.

Reporting on Provider Relief Fund Payments

PRF Reporting Period 3 (for funds received from January 1, 2021, to June 30, 2021) closed on September 30. Future Reporting Periods are as follows:

a. PRF Reporting Period 4 (for funds received from July 1, 2021, to December 31, 2021) will be January 1, 2023 to March 31, 2023.

b. PRF Reporting Period 5 (for funds received from January 1, 2022 to June 30, 2022) will be July 1, 2023 to September 30, 2023.

HRSA proposed to include two new reporting periods in its public comment request submitted to the Office of Management and Budget on September 21, 2022. These Reporting Periods would be as follows:

a. PRF Reporting Period 6 (for funds received from July 1, 2022 to December 31, 2022) would be from January 1, 2024 to March 31, 2024.

b. PRF Reporting Period 7 (for funds received January 1, 2023 to June 30, 2023) would be from July 1, 2024 to September 30, 2024.

Updates to Provider Relief Fund Requirements

In July 2022, HRSA updated its website and provided additional guidance related to allowable expenses, the alternative reasonable methodology, reporting on funds and HRSA audits.

Allowable Expenses

Recruiting and Retention Expenses. HRSA provided the following additional examples of allowable expenses under the PRF for "recruiting and retaining personnel": retention bonuses, incentive pay, mental health and stress management resources, overtime pay, employee referrals, and use of employment agencies.

Primary Care Provider Expenses. HRSA clarified that primary care providers can be reimbursed for their time and resources related to COVID-19 prevention outreach, education and counseling encounters that occurred in-person, virtually or electronically. However, if such activities are not directly associated with a scheduled patient encounter, provider services such as patient education, community outreach or expanding partnerships to support various priorities (e.g., identifying unvaccinated patients, expanding behavioral health services, etc.), they will not be reimbursed by the PRF.

Reporting on Funds

HRSA clarified that, when reporting the number of "Outpatient Visits" in the Reporting Portal, providers should also include outpatient surgical centers and a patient's home or residence." Further, HRSA noted that "[i]f providers are uncertain how to classify their encounters in one these groups, [HRSA] suggest[s] counting the unique encounters or visits among the most reasonable setting. For instance, an anesthesiologist who sees patients in both outpatient surgical centers and as part of inpatient procedures should separate the encounters between both inpatient admissions and outpatient visits. A home health provider can count their distinct home-based visits as outpatient visits."

Recoupment Appeal Process

On July 22, HRSA told Inside Health Policy that it had plans to unveil an appeal process for PRF recipients whose funds are being recouped by HRSA. HRSA has not provided updates with regard to this process as of the date of publication of this newsletter.

3. APPEALS OF FEMA PUBLIC ASSISTANCE PROGRAM DETERMINATIONS

On June 28, 2022, FEMA issued an advisory outlining a new process under which public assistance applicants may enter into agreements with state, local, tribal and territorial ("SLTT") government entities to carry out eligible emergency protective measures in cases where the SLTT entity is legally responsible for conducting the work. Under the agreement with FEMA, previously rejected expenses such as transportation, child care and housing will be eligible for reimbursement. In a press release that same day, Majority Leader Chuck Schumer explained that "FEMA will allow the state and impacted hospitals to enter into an agreement, like a Memorandum of Understanding, stating that the actions hospitals took to protect heroic doctors, nurses, support staff were in service of the state's legal responsibility to protect all New Yorkers, making those hospital expenditures eligible for FEMA's funding." A draft memorandum of understanding is in the works, and hospitals should consider appealing to FEMA any unfavorable payment determinations regarding such labor support costs.

LATEST ON 340B

1. POST-AHA CHANGES TO OUTPATIENT REIMBURSEMENT FOR DRUGS PURCHASED THROUGH 340B PLAN

After the Supreme Court's *AHA* decision holding that the agency's cuts in reimbursement for drugs purchased through the 340B Program violated the statute, the parties filed cross-motions before the District Court for the District of Columbia on the questions of 1) how 340B hospitals should be reimbursed for the remainder of 2022 in light of the Supreme Court's decision, and 2) how the agency should apply the Supreme Court's decision for payments made from 2018 to present for which the unlawful reductions in reimbursement to 340B hospitals were made. On September 28, 2022, the District Court ruled on the first question, holding CMS must begin making the correct 340B payments on a prospective basis for the remainder of 2022, which in briefing CMS stated should take two weeks to implement. To date, the court has yet to rule on payments from 2018 to present.

While the court addressed the 340B reimbursement policy for the remainder of 2022 only, in the CY 2023 OPPS proposed rule, CMS also discussed the issue of reimbursement to 340B hospitals for the purchase of outpatient drugs effective for calendar year 2023. In that proposed rule, CMS claimed that because it had already finalized the proposed rule prior to the court's decision and did not have time to change the payment rates, it is formally proposing to continue to pay 340B hospitals at a rate of ASP minus 22.5 percent for CY 2023, but states that the agency fully anticipates reverting to an ASP plus 6 percent policy for all hospitals in the final rule. If finalized as proposed, CMS would pay ASP plus 6 percent for all of 2023 and presumably for years going forward.

2. COURTS OF APPEALS TO DECIDE MANUFACTURERS' ABILITY TO RESTRICT 340B DISCOUNTS TO CONTRACT PHARMACIES

In October and November, the Third, Seventh and D.C. Circuit Courts of Appeals are all scheduled to hear argument in separate cases concerning whether pharmaceutical manufacturers are required to offer discounted 340B rates on products sold to contract pharmacies purchasing on behalf of 340B covered entities, including hospitals. The district courts in these appeals previously ruled that HRSA's May 2021 violation letters to the manufacturers must be rescinded for at least procedural reasons, but the courts have disagreed on the authority under the statute of manufacturers to restrict discounted prices to contract pharmacies at all. We anticipate decisions to be issued by the middle of 2023 in these cases.

LOOKING AHEAD

- Over the past year, economic headwinds for many nonprofit hospital systems and other providers have shifted unfavorably. Lasting impacts of COVID-19, including continued shutdowns, government restrictions on elective procedures and repayment obligations related to CARES Act funding, coupled with an overall market decline have left many healthcare borrowers in danger of defaulting under their debt obligations, as they are unable to meet required financial covenants. Such defaults are an industry-wide phenomenon that many healthcare organizations are facing. In light of these important issues, Ropes & Gray health care, public finance and restructuring attorneys will be discussing strategies to help borrowers who may find themselves facing the threat of debt default in light of these market conditions. Topics to be addressed will include strategies to avoid defaults, disclosure issues, bondholder/investor relations and restructuring considerations. Stay tuned for an upcoming Ropes & Gray webinar on the topic.
- We continue to see Medicare contractors disallowing reimbursement for hospitals' Nursing and Allied Health Education programs based on the contractors' conclusions that the hospitals are not the operators of the programs because some aspect of the program is not 100% in the hospital's control. Despite a federal district court ruling against the agency on this type of negative adjustment, *Medical University Hospital Authority v. Becerra*, 2021 WL 1177860 (D.S.C. March 29, 2021), it appears the agency is still directing Medicare contractors to closely review these programs and disallow reimbursement for them. For example, contractors have disallowed these payments where the hospital does not directly pay the trainees in the program, but contracts with a university or other entity to provide payroll services.
- On September 30, 2022, CMS sent the CY 2023 Final Outpatient Prospective Payment Rule to the Office of Management and Budget for review. We anticipate the final rule will be published in the coming weeks.
- Hospitals still await the agency's finalization of the August 2020 proposed rule on the treatment of Part C days in the DSH calculation for periods prior to October 1, 2013, following the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).
- Many health systems are looking to address the social, environmental and economic factors that have an outsized influence on health status and health outcomes but that fall outside the traditional clinical scope. This is particularly true for those participating in population health-model value-based care arrangements. From establishing new access points in underserved areas to partnering with payors, start-ups or community-based organizations, general counsel structuring such initiatives often face novel legal issues relating to data privacy and security, reimbursement program requirements, and fraud and abuse, among others. This was the subject of a roundtable discussion at Consero's Healthcare General Counsel Forum led by partner Ben Wilson and

is of interest to many of our clients. Stay tuned for an upcoming Ropes & Gray webinar on this topic.

- In mid-November on a Ropes & Gray podcast, partners Jane Willis (antitrust) and Stephanie Webster (health care) will discuss the recent rulemaking proposed by CMS regarding competition and transparency in healthcare. They will discuss how this rule is part of a broader effort in the Biden administration to aggressively enforce the antitrust laws, and in particular, what hospitals, healthcare systems and private equity-backed healthcare firms might expect from this rulemaking and the broader trend it represents.

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