



Charles N. Kahn III
President and CEO

September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals; 86 Federal Register 42,018 (August 4, 2021)

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, D.C and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Proposed Rule.

EXECUTIVE SUMMARY

OPPS Payment for 340B Purchased Drugs

The FAH reiterates its full support for CMS’s prospective budget-neutral 340B payment policy to continue to pay Average Sales Price (ASP) minus 22.5 percent for 340B-acquired drugs and to except rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. The FAH also supports CMS policy to maintain budget neutrality through an increase to the conversion factor by an amount commensurate with the savings generated by the 340B payment adjustment, though we believe the proposed 3.2 percent increase does not fully capture the current amount of savings and should be adjusted annually. We agree with CMS that this policy “better, and more appropriately, reflects the resources and acquisition costs that [340B] hospitals incur” while also ensuring that Medicare beneficiaries “share in the savings on drugs acquired through the 340B Program.” A study issued by Avalere Health notes that reversing the policy in 2021 would not only increase beneficiaries’ drug copayments by an estimated 37% on average, or \$472.8 million, at 340B hospitals, but would reduce net payments to 82% of all hospitals paid under the OPSS – including 89% of rural hospitals, 77% of rural 340B hospitals, 100 percent of rural sole community hospitals, and even 49% of all 340B hospitals.

Hospital Inpatient Only List

The FAH appreciates CMS’s thoughtful reconsideration of the FAH’s and other stakeholders’ comments that CMS received in the CY 2021 rulemaking cycle opposing the elimination of the IPO list and strongly supports CMS’s proposal to halt and reverse its elimination including returning to the list 298 services summarily removed. The IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing procedures on the IPO list receive the inpatient care and monitoring clinically warranted, and we would oppose its elimination over any timeline. Instead, the FAH strongly supports the case-by-case evaluation of procedures against CMS’s longstanding clinical criteria for removal. In addition, the FAH urges the Secretary to retain the current policy exempting procedures removed from the IPO list from certain medical review procedures and certain site-of-service claim denials until Medicare claims data indicate that the procedure is more commonly performed in the outpatient setting than the inpatient setting.

Requirements for Hospitals to Make Public a List of Their Standard Charges

The FAH continues to be supportive of price transparency initiatives that provide access to clear, accurate, and actionable information, but strongly opposes the proposed changes to the civil monetary penalty amounts as premature and inappropriate, especially in the midst of the ongoing public health emergency (PHE). Additional time and experience both during and after the COVID PHE are needed to determine whether current CMS educational and enforcement

authorities are sufficient, including, for example, the need to identify factors that will be considered in imposing a civil monetary penalty in any individual case.

The FAH also strongly opposes the proposal to prohibit the use of pop-up windows, before downloading a machine-readable file, that contain critical information and disclaimers for acknowledgment by the consumer. The pop-up windows disclose information that is critical to reducing the very real risk of consumer confusion of a contextless machine-readable file of standard charges and rates, and hospitals should be encouraged rather than dissuaded from providing these disclaimers.

COVID-19 Temporary Policies To Furnish Hospital Outpatient Services Remotely

The FAH appreciates that, in response to the COVID-19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement temporary policies to permit hospital staff to furnish mental health services remotely to Medicare beneficiaries in their homes, and we believe these temporary policies should be made permanent. These policies allow much greater and timely access to mental health services, especially in rural areas, for a vulnerable population. The FAH also supports making permanent the ability to furnish audio-only mental health services to address the unique needs of this patient population, especially amidst a persistent shortage of health care professionals in this critical specialty.

Proposed Recalibration of APC Relative Weights (II.A.)

Under section 1833(t) of the Act, CMS is required to annually review and revise APCs and their relative weights to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. CMS ordinarily uses the latest updates to the electronic claims file known as the Outpatient Standard Analytic File (SAF) and Medicare Hospital Cost Report Information System (HCRIS) to determine OPSS relative weights for the following fiscal year. However, the latest SAF from CY 2020 and the FY 2019 HCRIS files used to set the relative weights for CY 2022 would span the period of the COVID-19 PHE that began in the United States in March of 2020.

CMS’s analysis of this issue in the 2022 OPSS proposed rule is nearly identical to the analysis provided in the FY 2022 IPSS proposed rule. In summary, CMS concludes that the data normally used to set OPSS rates is atypical because of the COVID-19 PHE and the data anomalies will have a material effect on the OPSS relative weights. For these reasons, CMS proposes to use 2019 SAF data and FY 2018 Medicare hospital cost reports to set the 2022 OPSS relative weights and for other purposes. **FAH agrees with CMS’s proposal to use the 2019 SAF data and FY 2018 Medicare cost reports to set the CY 2022 OPSS relative weights.**

In the FY 2022 IPPS rule, CMS indicated that it believes FY 2021 Medicare utilization is likely to return to its pre-pandemic norm and be available to set FY 2023 IPPS rates. Since CMS made that statement, circumstances have changed in many areas of the country. While an increasing number of Americans were obtaining a COVID vaccination in the first six months of 2021, the rate at which vaccinations were being sought slowed considerably into the summer. At the same time, the COVID Delta variant has led to a reemergence of a high rate of infections, hospitalizations, and deaths in many areas of the nation—particularly those areas where vaccination rates are low. FAH believes it is significantly likely that CMS may need to consider using pre-pandemic claims and cost report data to set the IPPS and OPSS rates for FY 2023 and CY 2023 respectively.

There is one other issue that FAH asks CMS to consider for the CY 2022 OPSS final rule. CMS's traditional practice would be to apply a weight scaler (a budget neutrality adjustment) to ensure that the average case weight for the payment year (CY 2022) is equal to the average case weight from the base year (CY 2021) using a single year of utilization. This weight scaler is applied so that the revised relative weights for CY 2022 do not increase or decrease payments compared to the CY 2021 relative weights. For CY 2022, CMS proposed a weight scaler of 1.4436.

By using CY 2019 utilization in place of CY 2020 data, the base year weights (CY 2021) will not reflect any changes in case mix that would occur from using CY 2020 compared to CY 2019 utilization. Thus, CMS will be making the payment year weights (CY 2022) budget neutral to a base year that does not reflect any change in real case mix as would normally occur. If CMS were to duplicate this policy for FY 2023, absent any intervention, CMS would be applying a normalization factor that does not allow for any real changes in case mix for two years.

If CMS were then to return to its normal practice of using the latest available utilization data (CY 2022 utilization for CY 2024), CMS would then be scaling the relative weights to a base that reflects a 3-year change in real case mix (CY 2019 through CY 2022). FAH requests that CMS consider whether to reflect an adjustment to the base year average case weight for an increase in case mix between CY 2019 and CY 2020 that would occur if CMS were to follow its normal practice (e.g., scale to a base year average case weight that is increased by average real increase in annual case mix).

Proposed Wage Index Changes (II.C.)

The FAH commends CMS's continued commitment to supporting rural hospitals by mitigating the negative feedback loop created by the wage index through an increase to the wage index values of low wage index hospitals. Rural hospitals are imperative in ensuring access to care for the more than 60 million Americans living in rural areas across the United States, including close to one quarter of all Medicare beneficiaries. Because Medicare beneficiaries disproportionately rely upon rural hospitals for care, Medicare reimbursement tends to impact rural hospitals' revenue more than non-rural hospitals. As CMS has previously noted in the FY 2020 IPPS rulemaking, the wage index has created a "downward spiral" whereby low wage index hospitals receive lower reimbursement, thereby weakening their capacity to invest in

recruitment or employee retention, and further depressing reimbursement. As such, the FAH commends CMS's proposal to continue its policy of increasing the wage index values for hospitals in the lowest quartile of the wage index values across all hospitals. *The FAH, however, strongly recommends that CMS reverse its budget neutrality adjustment associated with the low wage index hospital policy and instead apply the policy in a non-budget neutral fashion for CY 2022 – which we believe CMS has authority to do.* Non-budget neutral implementation of this policy would avoid unnecessarily reducing OPPS reimbursement, particularly in the midst of the ongoing COVID-19 pandemic.

Proposed Adjustment for Rural Sole Community Hospitals (I.E.)

The FAH supports CMS's proposal to provide this important payment adjustment. These hospitals are typically the chief, if not sole, source of community outpatient care for rural residents and this adjustment is vital to ensuring continued access to the care they need.

CY 2022 OPPS Payment Methodology for 340B Purchased Drugs (V.B.6.)

The FAH reiterates its full support for CMS's prospective budget-neutral 340B payment policy to continue to pay Average Sales Price (ASP) minus 22.5 percent for 340B-acquired drugs and to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. The FAH also supports CMS policy to maintain budget neutrality through an increase to the conversion factor by an amount commensurate with the savings generated by the 340B payment adjustment, though we believe the proposed 3.2 percent increase does not fully capture the current amount of savings and should be adjusted annually. Further, the FAH reiterates its position that if further judicial review of that policy were to result in a retrospective reversal of the policy, the Medicare Act does not permit CMS to make any prospective offsets to achieve actual or retrospective budget neutrality, nor does it permit any recoupment of payments made for nondrug items and services in prior years. Finally, the FAH supports CMS's proposal to continue to pay ASP+6 percent for drugs or biologicals that were not purchased with a 340B discount.

In 2018, CMS took an important step to directly benefit seniors and improve the accuracy of Medicare's payment for outpatient hospital services across all hospitals treating Medicare beneficiaries. The agency said it was implementing this change to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur" while also ensuring that Medicare beneficiaries "share in the savings on drugs acquired through the 340B Program." We believe the policy has achieved this important goal and advanced Congressional intent underlying the OPPS statute to promote efficiency, equity, and patient-centered care through, for example, reduced copayments for Medicare beneficiaries, especially for cancer patients.

That action, to better align Medicare payment with 340B hospital acquisition costs, had two immediate benefits. First, seniors who get their drugs at a 340B hospital pay less because the lower Medicare OPPS payment to the hospital means a lower copayment for the Medicare

beneficiary. This is due to the Medicare copayment structure, which requires seniors to pay 20% of the amount Medicare reimburses the hospital, not 20% of what it costs the hospital to buy the drugs. The prior payment policy resulted in a significant, negative impact on beneficiaries. Because Medicare payment rates far exceeded 340B hospitals' acquisition costs, beneficiaries were making disproportionately large coinsurance payments compared to 340B hospitals' costs of acquiring the drugs. A study issued by Avalere Health (Attachment A) earlier this year notes that reversing the CMS 340B payment policy in 2021 would increase beneficiaries' drug copayments by an estimated 37% on average, or \$472.8 million, at 340B hospitals.

Second, all hospitals, including 340B hospitals, get a much-needed 3.2 percent bump in Medicare payment for primary and emergency care, as well as outpatient procedures and other non-drug services – a welcome increase in a chronically underfunded system. The inefficiencies of the pre-2018 drug payment policies had tangible impacts on non-340B hospitals and the communities they serve. Because of the OPSS prospective payment budget neutrality requirement, the gains realized by 340B hospitals as a result of the mismatch between acquisition costs and payment rates came at the expense of non-340B hospitals, who received lower OPSS payments to account for the comparatively inflated payments relative to costs to 340B hospitals. The pre-2018 OPSS payment rates to non-340B hospitals increased the financial burden of providing outpatient services, by requiring non-340B hospitals to effectively subsidize the provision of similar services to 340B hospitals serving comparable patient populations. Along those lines, the Avalere study examined FY 2018 Medicare cost reports to compare levels of a critical measure of community benefit – uncompensated care. Its finding: non-340B hospitals had marginally higher uncompensated care cost rates – 4.4 percent of total operating costs – than 340B hospitals – 4.2 percent.

CMS's actions level the playing field across all OPSS hospitals, reinforcing the purpose of the Medicare OPSS to incentivize efficient and equitable behavior. If, however, CMS's current 340B payment policy for separately payable drugs were reversed, and the corresponding 3.2 percent increase to the base rate for all non-drug OPSS services to all OPSS hospitals were removed, the negative hospital impact is staggering: 82% of all hospitals paid under the OPSS – including 89% of rural hospitals, 77% of rural 340B hospitals, 100 percent of rural sole community hospitals, and even 49% of all 340B hospitals – would experience a net payment decrease in 2021 based on Avalere's estimates. The negative impact to rural hospitals, struggling to survive and closing at an alarming rate, would be particularly damaging.

Importantly, CMS's Medicare OPSS payment change does not affect the 340B Program administered by the Health Resources & Services Administration nor hospitals' ability to participate in it. Indeed, apart from Avalere's finding that the CMS policy provides a net payment benefit to approximately half of 340B hospitals, they continue to benefit under Medicare's OPSS from the significant discounts they get when they purchase drugs through that program. That is because even with a payment rate of ASP minus 22.5 percent, given the average discount of 34 percent cited by MedPAC in its March 2016 Report to Congress, 340B hospitals receive a payment materially greater than the acquisition costs, lending support to a key

purpose of the 340B program – to “stretch scarce Federal resources,” while at the same time enabling Medicare beneficiaries to share in the savings, which the 340B program does not require.

Payment for Partial Hospitalization Services (VIII.B.)

The FAH supports use of the CY 2021 payment rates for partial hospitalization as the cost floor for CY 2022 rates as well as use of CY 2019 data to calculate the CY 2022 rates. The FAH agrees with CMS’s assessment that the COVID-19 PHE continues to disrupt the provision of partial hospitalization program (PHP) services at a time when access to these services is more critical than ever. While the PHE has magnified the need for improved access to behavioral healthcare, there are severe shortages of behavioral healthcare providers in many parts of the United States. The payment rate methodology outlined in the proposed rule should help lessen the impact of COVID-19 on providers of partial hospitalization services.

Proposed Changes to the Inpatient Only (IPO) List (IX.)

The FAH strongly supports CMS’s proposal to halt and reverse the elimination of the inpatient only (IPO) list, which designates those procedures not payable under the OPPTS because they can only be appropriately provided on an inpatient basis. As we stated in our CY 2021 comments opposing the proposed elimination, the IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing procedures on the IPO list receive inpatient care and monitoring. We appreciate CMS’s thoughtful reconsideration of the FAH’s and other stakeholders’ comments that CMS received in the CY 2021 rulemaking cycle opposing the elimination of the IPO list and encouraging CMS to retain the agency’s prior methodology for evaluating and removing procedures based on clinical criteria.

The FAH also strongly supports CMS’s proposal to return the 298 services summarily removed from the IPO list in CY 2021 to the IPO list for CY 2022, and the FAH supports CMS’s renewed utilization of its longstanding removal criteria that the agency historically used to ensure beneficiary safety. We agree with CMS’s considered determination “that none of these removed services have sufficient supporting evidence that the service can be safely performed on the Medicare population in the outpatient setting.”¹ The FAH continues to support CMS’s previously longstanding process for removing procedures from the IPO list based on annual and case-by-case application of five clinical and patient safety-oriented criteria. Further, we support CMS’s proposal in this Proposed Rule to codify these removal criteria in a new § 419.23.

CMS also requests comment on whether CMS should maintain a longer-term objective of eliminating the IPO list or systematically scale back the IPO list. The FAH continues to oppose elimination of the IPO list over any timeline, as it would create inappropriate safety risks for Medicare beneficiaries, impose administrative burdens on physicians and hospitals, increase beneficiaries’ financial burden, and erode the value of Part A coverage. Furthermore, the IPO list

¹ 86 Fed. Reg. at 42,159.

does not operate to impede innovation in surgical care, as the IPO list has evolved with advances in surgical techniques and surgical care protocols. Instead, the FAH strongly supports the case-by-case evaluation of procedures against CMS's longstanding clinical criteria for removal.

Medical Review of Inpatient Hospital Admissions for Procedures Removed From the IPO for CY 2022 and Subsequent Years (X.A)

Although the FAH strongly supports retaining the IPO list and returning the 298 services removed from the IPO list in CY 2021, *the FAH urges the Secretary to retain the current policy exempting procedures removed from the IPO list from certain medical review procedures and certain site-of-service claim denials until Medicare claims data indicate that the procedure is more commonly performed in the outpatient setting than the inpatient setting.* Under the current policy, the Secretary looks at changes in actual clinical practice to identify the point at which medical review activities to assess compliance with the 2-Midnight rule becomes appropriate in lieu of formulaically applying a two-year exemption from medical review. In some cases, a procedure removed from the IPO list may be more commonly performed in the inpatient setting for a number of years, while in other cases, the shift to the outpatient setting may be more rapid due to significant medical advancements. This variability favors an evidence-based exemption that extends until the procedure is performed more than 50 percent of the time in the outpatient setting.

Comment Solicitation on Temporary Policies To Address the COVID-19 PHE (X.D.)

In response to the COVID-19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement a number of temporary waiver policies to address the pandemic, including policies to prevent spread of the infection and support diagnosis of COVID-19. CMS seeks comment on whether certain temporary policies, as discussed in the OPSS proposed rule, should be made permanent. The FAH appreciates the opportunity to provide our views on these waiver policies as discussed further below. We also note that we look forward to commenting more thoroughly, including regarding any potential guidelines to ensure clinical appropriateness, as more specific proposals to permanently extend certain waiver policies are developed.

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in their Homes

Medicare Coverage of Mental Health Services Via Remote Technologies

The FAH supports permitting the provision of mental health services, including PHP services, furnished remotely by hospital staff to beneficiaries in their homes beyond the COVID-19 PHE. FAH member hospitals have extensively provided these services to patients at home during the PHE and believe that mental health services are well-suited for remote delivery via communication technology, while providing important clinical benefits for patients. In addition, patients across the United States suffer from the serious shortage of qualified mental health providers in this country. This compromises the ability of patients to get timely access to care,

and sometimes requires patients to travel long distances for necessary services. The delays associated with provider scarcity have significant negative consequences on health. For example, individuals are likely to develop more acute mental illness when they do not receive needed and timely interventions, ultimately leading to increased suffering for patients and their families, as well as higher burdens on the health care system. The use of communications technology offers an opportunity to interrupt a cascade of negative outcomes by ensuring that care is available promptly.

Multiple studies support the need for ongoing flexibility and expanded coverage of telehealth for mental health services. For example, previous epidemics have shown that the impact on mental health and substance use will continue for years to come.² Further studies demonstrate that telehealth is particularly effective in mental healthcare delivery.³ This is true for PHP services delivered via telehealth as well. A recent comparative effectiveness study demonstrated that the only significant differences between those who participated in PHPs via telehealth technologies and those who attended in person was that those who participated via telehealth had greater lengths of stay and were more likely to stay in treatment until completed.⁴

Other studies have shown that various types of mental health services, often delivered through PHPs, can be provided effectively via telehealth including depression screening, follow-up care after hospitalization, behavioral counseling for substance use disorders (SUD), medication management, and psychotherapy for mood disorders.⁵ Telehealth has been found to increase retention for SUD treatment, including medication treatment, especially when treatment is not otherwise available or requires lengthy travel.⁶ In addition, there is evidence of reduced

² Hawryluck L, Gold WL, Susan, S: SARS Control and Psychological Effects of Quarantine, Toronto, Canada. *Emerg Infect Dis.* 10;7: 1206–1212 (July 2004); Reardon S: Ebola's mental-health wounds linger in Africa: health-care workers struggle to help people who have been traumatized by the epidemic. *Nature*, 519; 7541:13 (2015); Goldmann E, Galea S: Mental health consequences of disasters. *Ann Rev Public Health*, 35:169–83 (2014). Available online at https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-032013-182435?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Aacrossref.org&rfr_dat=cr_pub%3Dpubmed.

³ Mace S, Boccanelli A, Dormond M: The Use of Telehealth within Behavioral Health Settings: Utilization, Opportunities, and Challenges. Behavioral Health Workforce Research Center, University of Michigan, (March 2018) Available at https://behavioralhealthworkforce.org/wp-content/uploads/2018/05/Telehealth-Full-Paper_5.17.18-clean.pdf; Bashshur RL, Shannon GW, Bashshur N, Yellowlees PM: The empirical evidence for telemedicine interventions in mental disorders. *Telemed J E Health*, 22(2): 7-113 (Jan. 2016).

⁴ Zimmerman M, Terrill D, D'Avanzato C, et al.: Telehealth Treatment of Patients in an Intensive Acute Care Psychiatric Setting During the COVID-19 Pandemic: Comparative Safety and Effectiveness to In-Person Treatment. *J Clin Psychiatry.* 82(2) (2021). Available at <https://www.psychiatrist.com/jcp/covid-19/telehealth-treatment-patients-intensive-acute-care-psychiatric-setting-during-covid-19/>.

⁵ National Quality Forum and AHA Center for Health Innovation: Redesigning Care: a How-To Guide for Hospitals and Health Systems Seeking to Implement, Strengthen and Sustain Telebehavioral Health. (2019). Available at <https://www.aha.org/system/files/media/file/2020/03/Telebehavioral-Health-Guide-FINAL-031919.pdf>.

⁶ Lin L, Casteel D, Shigekawa E, et al.: Telemedicine-delivered treatment interventions for substance use disorders: A systematic review. *Journal of Substance Abuse Treatment*, 101: 38-49 (June 2019).

utilization of higher-cost services associated with providing access to mental healthcare services via telehealth technologies.⁷

The experience of our members in delivering mental healthcare services, including PHP services, during this pandemic is consistent with these research studies. They have been able to continue providing mental health and addiction treatment services during the pandemic and have experienced significantly reduced missed appointments by patients. In addition, telehealth has enabled patients and family members who do not have PHPs in their communities to access these services remotely which has significantly improved access to a level of care that is simply not otherwise available in most communities, especially in rural areas.

Medicare Coverage of Mental Health Services Via Audio-Only Telehealth

To further promote access to mental health services, especially in light of the persistent shortage of mental health care professionals, the FAH also supports making permanent the ability to furnish audio-only mental health services (including PHP services). Our members are concerned that many of their more vulnerable patients are unemployed, under-employed, homeless, or reside in geographic areas and populations without widespread access to broadband. Further, there may be circumstances in which a patient is unable or does not wish to use two-way, audio/video technology, or when furnishing services via audio-only technology is necessary in the physician or practitioner's clinical judgment. Establishing a standard based on clinical judgment accounts for the wide range of potential circumstances when audio-only services are appropriate. A rigid rule-based approach likely would stifle innovation in care delivery and undermine telehealth's potential to expand access to services in a specialty plagued by severe provider shortages.

Finally, coverage of audio-only telehealth services can help fill gaps in care by enabling underserved and vulnerable populations to access mental health services. Importantly, beneficiaries and providers have become more familiar with and better equipped to use telehealth, including audio-only telehealth. Among Medicare beneficiaries who had a telehealth visit last summer and fall, over half of them accessed care using a telephone only.⁸

⁷ Shigekawa E, Fix M, Corbett G, et al.: The current state of telehealth evidence: A rapid review. *Health Affairs*, 37(12): 1975-1982 (2018).

⁸ Koma W, Cubanski J, Neuman T: Medicare and Telehealth: Coverage and Use During the Covid-19 Pandemic and Options for the Future. Kaiser Family Foundation, (May 2021). Available at <https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/>.

Clarification Regarding “Incident To” Services in Hospital Outpatient Programs

As CMS points out in the proposed rule, certain types of health care professionals (e.g., counselors and other licensed professionals) are qualified to provide services, such as psychoanalysis and psychotherapy, but are not authorized to bill Medicare directly. This policy creates a significant coverage gap since these practitioners provide much of the care related to behavioral health services and as discussed above behavioral healthcare settings have been struggling with workforce shortages at unprecedented levels.

The proposed rule discusses how services by counselors and other hospital staff who may not directly bill Medicare may nevertheless be billed by hospitals under the OPPS or supervising physicians or other practitioners as “incident to” their professional services under the physician fee schedule. This discussion highlights how PHPs can extend the capacity of certain higher credentialed clinicians by having additional practitioners provide services under their supervision – and this practice should be permitted to continue via telehealth or remote technologies after the conclusion of the PHE.

Coverage of Facility Fees for PHP Services Provided Via Telehealth

We appreciate that CMS has recognized the need to cover facility fees for Medicare outpatient services, including PHP services, that are provided via telehealth. In the interim final rule issued at the end of last April, CMS recognized that when a physician or practitioner who ordinarily practices in a hospital outpatient department furnishes a telehealth service to a patient who is located at home, the hospital still must provide administrative and clinical support for that service. These additional administrative and ancillary services include scheduling, record-keeping, assisting beneficiaries with technological challenges, and other support services. As Medicare coverage continues for hospital outpatient services, including PHP services, provided via telehealth, it will be critical to continue covering administrative and other clinical support provided by the facility that are also critical for ensuring continued improved access to these services for Medicare beneficiaries.

2. Direct Supervision by Interactive Communications Technology

Due to the PHE, CMS has waived the requirement for direct supervision to be provided through the physical presence of a physician or non-physician practitioner for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. The direct supervision requirement may be met through a virtual presence with audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or practitioner.

The flexibility to provide direct supervision through real-time audio/video technology should be made permanent. In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic,

or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to transfer the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

When the current policy is made permanent, there should not be a requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track whether and to what extent they supervised through telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified. Thus, the FAH requests that the definition of direct supervision be permanently amended to allow for telehealth supervision, without the requirement for a new modifier.

3. Payment for COVID-19 Specimen Collection in Hospital Outpatient Departments

CMS created HCPCS code C9803 for COVID-19 specimen collection to be used only during the COVID-19 PHE and only when no other service is provided by the hospital except a clinical diagnostic laboratory test. CMS previously stated its intent to retire this code at the conclusion of the PHE, but it is requesting comment on whether the agency should continue this code and payment beyond the conclusion of the COVID-19 PHE.

The FAH supports maintaining this code as testing for COVID-19 likely will continue beyond the conclusion of the PHE. CMS may want to consider defining the code more broadly so that it can apply to swabs for other types of testing as there is no specimen collection code for any type of swabbing of the nose.

Additions to the List of ASC Covered Surgical Procedures (XIII.C.1.d)

The FAH strongly supports CMS's proposal to reinstate the criteria and process for adding procedures to the ASC Covered Surgical Procedures List (CPL) that was in effect prior to CY 2021, as well as CMS's proposal to remove 258 of the 267 procedures added to the ASC-CPL in CY 2021. We appreciate CMS's thoughtful reexamination of the ASC-CPL policy it adopted for CY 2021, clinical review of the 267 procedures added to the ASC-CPL in CY 2021, and consideration of the FAH's and other stakeholders' comments expressing concern over removal of the specifications for the ASC-CPL. As we explained in our CY 2021 comments, the general standards and exclusion criteria in effect in CY 2020 have allowed the ASC-CPL to evolve and expand with surgical advancements while ensuring that procedures that continue to pose significant patient safety risks are restricted to the hospital setting.

As CMS notes, there are “significant differences” between the ASC and hospital outpatient department setting, and thus there are procedures that can be furnished in a hospital outpatient department setting that are not safe and effective in an ASC setting.⁹ The ASC-CPL exclusion criteria that CMS proposed to be reinstated reflect these critical differences between hospital outpatient departments and ASCs. By way of example, proposed § 416.166(c)(5) excludes surgical procedures that commonly require systemic thrombolytic therapy. These procedures pose significant patient risks that require rapid intervention in a hospital setting in the event of complications, including embolization and stroke. Despite significant advancements in surgical care, the risks of systemic thrombolytic therapy continue to be significant, and the categorical exclusion of procedures requiring such therapy from the ASC-CPL continues to be appropriate. Likewise, the other exclusion criteria at issue—which cover surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, or are generally emergent or life-threatening in nature—are appropriate and necessary to ensure the safety of ASC-CPL procedures for performance in an ASC.

Request for Information (RFI): Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability (FHIR) in Outpatient Quality Programs (XIV.)

CMS poses numerous questions about moving to a fully digital quality enterprise by 2025 across its quality and value-based purchasing programs.¹⁰ The agency indicates that feedback received will be used solely for planning purposes, and that any subsequent updates to specific quality programs would occur through rulemaking. CMS describes an overarching goal of giving access to transparent and timely quality of care information to all of the intended users of their data, subject to privacy and security safeguards. By so doing, CMS envisions that patients, providers, policymakers, and payers will be empowered as participants in a value-driven health system. Foundational concepts for transforming the agency’s quality enterprise discussed in this RFI include the following: data standardization, interoperable health information exchange, adoption of emerging health information technology (health IT), data accessibility, data aggregation, enhanced patient voice, and alignment.

In response to increasing demand and rising expenditures, Medicare has embarked on transitioning from a Fee-for-Service (FFS) structure to value-based purchasing (VBP). Value is defined by both costs and quality of care, and quality measurement requires health care data. Data are plentiful but often not useful: they are fragmented, cannot be shared across the care continuum and cannot be accessed by all of a beneficiary’s clinicians and other providers. Data collection routinely is burdensome and costly. Measure results are not always transparent, comprehensible, timely, and actionable for providers and patients.

The FAH welcomes the opportunity to respond to this RFI. We have long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of

⁹ 86 Fed. Reg. 42,208.

¹⁰ Hereafter in this section “quality programs” will have the meaning of CMS-administered quality and value-based purchasing activities, unless otherwise specified.

meaningful, actionable information that support and enhance patient care within and across settings. We also have favored moving forward expeditiously with proposals to improve electronic health information exchange whenever health IT advances can facilitate improved quality and access to care while being cost-effective and without introducing provider burden.

General Considerations

The FAH commends CMS for thinking strategically and aspirationally about its quality enterprise. The agency is well-positioned in many ways to be a leader in this arena: a broad-based portfolio of quality programs yielding abundant data; a funded laboratory for testing value-based interventions (i.e., the CMS Innovation Center (CMMI)); an established close working relationship with the Office of the National Coordinator for Health Information Technology (ONC)); the ability to sponsor public-private partnerships; a clear responsibility to beneficiaries to ensure their optimal care; an equally clear responsibility to the Congress to be fiscally prudent with finite taxpayer resources; and the leverage that accrues to being a dominant health care payer. The future of health information exchange clearly is digital, and CMS appropriately is looking ahead. Our comments are founded on the following principles:

- First and foremost, the CMS digital strategic plan must support a system in which data are collected and reported once and only once, regardless of the number of downstream uses of the data.
- Only those measures that truly make a difference in patient health and are predictors of value should be implemented in CMS quality programs.
- Quality program measures, policies, and regulations must reflect the patient’s voice whenever feasible.
- Public reporting of provider data should be transparent and focused on those that are reliable, valid, and useful for patients and their families. Adoption of health IT advances by CMS must be aligned with the real-world practice of medicine and related requirements must be consistent between the hospital and physician promoting interoperability programs.
- Patients and their representatives should have prompt access to their electronic health information with minimal effort.

Definition of Digital Quality Measures

CMS notes having previously described digital quality measures (dQMs) as measures which originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems.¹¹ Potential sources cited by CMS for dQMs are diverse, such as EHRs and wearable devices. In this RFI, CMS asks for feedback on and enhanced definition, such that a dQM would be “a software that processes digital data to produce a measure score or measure scores”. CMS indicates its view that the updated definition would

¹¹ Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>.

facilitate the deployment of dQMs to interface with application programming interfaces (APIs) based on Health Level 7's Fast Healthcare Interoperability Resources standards (HL7® FHIR®).

The FAH supports the additional clarity and specificity that is offered by the enhanced definition. Standardized and clear definitions for all terms in all phases of the digital transformation initiative will be necessary. (We note that a later section of this RFI offers more details about potentially desirable characteristics of dQMs that we will address further below.) We are particularly appreciative of the broad interpretation that CMS has provided for potential sources of data for use in dQMs.

Use of FHIR® for Current eQMs

CMS reiterates that stakeholders continue to express concerns about the current state of eQMs reporting: technology barriers, imposed provider burden, and associated costs. In response, the agency has been exploring the utility of FHIR® as a framework for eQOM structure and data submission and has started converting some current eQMs to the FHIR® standard and testing the converted measures.

The FAH thanks CMS for responding to concerns we and others have voiced about current eQOM reporting by exploring potential solutions such as the FHIR® standard. We would ask that CMS promptly share examples of the converted measures and share testing results that demonstrate real world applications (e.g., across a wide range of vendor systems, facility sizes and locations) and not wait until all measures have been converted and tested. It is difficult for us to comment intelligently whether eQOM conversion to FHIR® is a valuable and burden-reducing strategy without such information. If conversion to FHIR®-based eQMs will entail revised measure specifications and changed data submission processes, we respectfully suggest that CMS promptly begin a moratorium on new and revised eQMs and the current associated reporting and scoring requirements and policies until the FHIR®-based measures are available for comment through rulemaking. Also, the previously finalized increases to the number of measures and reporting quarters for the CY 2022 EHR reporting period and future years should be paused indefinitely as CMS introduces the FHIR®-based measures and providers become facile with their reporting.

With regards to the question of the potential benefits of “real-time quality measure scores,” we again cannot answer meaningfully without more information from CMS, such as a fuller description of what is meant by “real-time” and examples of measures for which such scores might become available. At present, our members would find great value simply in receiving more frequent, reliable, and comprehensible feedback about their performances on current measures.

Changes under Consideration to Advance Digital Quality Measurement

CMS describes requiring data for use in EHR-derived measures to be standardized, interoperable, and suitable for acquisition using FHIR®-based APIs. CMS notes the potential opportunity to capture types of data beyond traditional clinical, administrative, and claims data through standards-based APIs. CMS also states a commitment to validation of digital data

submitted to the Hospital Inpatient Quality Reporting (Hospital IQR) program for completeness, accuracy, alignment with standards, and data cleaning.

The FAH conceptually agrees that data for use in dQMs should be standardized and interoperable. We note that standardization should not be overemphasized to the point of negating the utility of the data for specific CMS quality programs; for example, appropriate data for some inpatient hospital measures may differ from what is optimal for some post-acute care measures. Flexibility to define nuanced data requirements when appropriate should not be sacrificed to standardization. The FAH further conceptually supports that digital data for use in CMS quality programs should also be interoperable, but we again recommend retaining flexibility should conflicts arise between standardization and interoperability. We fully support the agency's commitment to incorporating robust data validation as part of its digital quality strategy.

We acknowledge the potential for FHIR®-based standards as part of a digital quality strategy, but we are reluctant at this time to agree definitively that they are the best choice without at least an outline of how the digital strategy might be implemented for at least one of the existing CMS quality programs. We are somewhat disturbed by what appears to be a clear commitment by CMS to proceeding with FHIR®-based standards in the agency's quality programs as evidenced by the extensive materials outlined at https://ecqi.healthit.gov/FHIR®?qt-tabs_FHIR®=2, when CMS ostensibly through this RFI is seeking input about the utility and propriety of such commitment. In addition, as new and improved standards become available, this strategy should be designed to evolve and adapt to include them where appropriate.

Building on its enhanced definition of a dQM as “a software that processes digital data to produce a measure score or measure scores,” CMS states a belief that its future dQMs should be self-contained, end-to-end reporting tools that are able to perform three functions:

- Retrieve data from primarily FHIR®-based resources maintained by providers, payers, CMS, and others via automated queries from a broad set of digital data sources;
 - Starting with EHRs
- Calculate measure score(s); and
- Produce measure score reports.

CMS also provides a detailed list of additional desirable properties and functionalities for its dQMs.

The FAH has no objections to the aspirational list of dQM properties, but we are unable to comment further in the absence of examples from the agency of potential dQMs.

Building a Pathway to Data Aggregation in Support of Quality Measurement

CMS suggests that the current challenge of data fragmentation might be addressed through policies that incorporate data aggregators into the dQM reporting process and mentions health information exchanges (HIEs) and qualified clinical data registries (QCDRs) as potential

aggregators. CMS indicates that data aggregation policies would be developed to maintain the integrity of its measure-reporting process.

The FAH supports incorporation of data aggregators into digital quality reporting within CMS programs. Our members have suggested to us that aggregation by HIEs and/or others may, in addition to serving as a repository collating fragmented data, have the capabilities to partially overcome variable submission requirements by entities such as state public health agencies. For example, easy and inexpensive access to aggregators potentially could obviate the adoption of FHIR® standards, as a prerequisite to usable PDMP information exchange. However, we note that currently data aggregators are unevenly distributed geographically, and their services are costly, making their use infeasible for many providers, especially those that are smaller or in rural locations. We encourage CMS to further explore the potential impact that this shift may have such as the potential number of data aggregators with whom one facility may be required to exchange data and the associated costs and resources required for this data sharing. Creating a new source of reporting burden would be contrary to the goals of this strategy and additional guidance and solutions may be needed to minimize or eliminate these concerns.

Potential Future Alignment Across Reporting Programs, Federal and State Agencies, and the Private Sector

CMS states a commitment “to using policy levers and working with stakeholders to solve the issues of interoperable data exchange” as part of transforming its quality measurement enterprise to be digital. CMS describes the “future potential development and multi-staged implementation” of a common dQM portfolio across its own programs and extending to those of other governmental agencies and private payers and seeks input on priority areas of focus (e.g., measure requirements, data standards).

The FAH enthusiastically welcomes this commitment by CMS to fully align within its programs wherever feasible and appropriate. The implications for reduced provider burden and costs are substantial.

We are concerned about the lower priority and prolonged timeline given the agency’s use of language such as “future potential development and multi-staged implementation.” Our members view alignment as a priority at least on par with interoperability. We strongly recommend that CMS commit to using policy levers to solve the issues of alignment, not just those of interoperable data exchange. We further strongly recommend that CMS move actualizing this commitment to top line priority status and begin now to do so across its quality measurement enterprise, related Department of Health and Human Services (HHS) activities, and other federal health care programs (e.g., military and veterans’ health care). We would view further delay of CMS, HHS, and other federal alignment to reach the worthy but aspirational goal of extending alignment across all states and all payers as unacceptable. Finally, we fully support the continued importance of the roles played by the National Quality Forum (NQF) and the NQF-convened Measures Application Partnership (MAP).

In response to the agency’s query about priority areas of focus (e.g., measure requirements, data standards), the FAH recommends a more holistic but targeted approach. We

have some concern about the utility of a strategy that focuses first on a quality program component (e.g., requirements) in isolation and the implied sequential development of the remaining components. Instead, we strongly suggest a strategy of choosing a few, well-established, validated, and meaningful measures for which a digital implementation model for use within one CMS program can be created and tested, optimally in a real-world setting (e.g., voluntary provider participation that is incited by exemption from multiple current requirements and awarding of full PIP scoring credit) or at least in robust and transparent simulation. Lessons learned could then be used in a rapid-cycle fashion to accelerate this important work.

Conclusions

The FAH recommends that CMS undertake the following near-term actions:

- Aggressively pursue alignment of quality initiatives across CMS, HHS, and other federal health care programs;
- Promptly share with all stakeholders the design and results of CMS efforts to convert current eQMs to dQMs;
- Design and test proof-of-concept models and feed testing results into a rapid-cycle process;
- Convene appropriate stakeholders to make recommendations about the role of data aggregators; and
- Adopt as a fundamental tenet that providers be required to collect and report the data only one time.

Additionally, the FAH concludes our comments with several key points as follows:

- We applaud the strategic thinking and proactivity by CMS as evidenced in this RFI. The RFI is consistent with our repeated recommendation for periodic, holistic assessment of the PIP's success in meeting its intended goals of better patient care, reduced provider and patient burden, and reduced costs.
- We agree that the future is digital. However, if the next step of the process is an actual ongoing dialogue with stakeholders (which is much needed), rather than a proposal of major revisions to specific programs, the total transformation of CMS quality programs as described in this RFI by 2025 is unrealistic.
 - The agency should more often follow a pathway of evolution than revolution.
 - Trials of well-focused model initiatives with rapid-cycle learning seem most appropriate.
 - Overreliance on a single system, approach, or standard (e.g., FHIR®) should be avoided until successful model elements can be identified.
 - Changes and timelines should be considered in the context of how health care delivery stabilizes into a post-COVID-19 PHE “new normal.”
 - CMS should actively monitor the progress of the numerous public and private initiatives in this arena and allow them reasonable time to mature before imposing CMS's solutions.
- The special interoperability challenges of smaller, rural, and other providers with more constrained resources must be addressed.

- We concur with CMS that better understanding of the patient’s role as an active EHR end-user could point the way to health information exchange that is structured to be more useful to patients in health care decision-making and is more likely to result in patient activation.
 - Facilitating inclusion of PROMs and PGHD could add value.
 - Privacy and security of patients’ health information must be ensured.
 - Use of a “self-reported health” measure as an enterprise-wide metric of CMS quality program success should be promptly explored.
- There will be significant costs to “going digital”. Who will bear those costs?

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program (XV.)

B. Proposed Hospital OQR Program Quality Measures

- Measure Removal

CMS proposes the removal of two measures beginning with CY 2023 reporting period:

- Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival (OP-2) and
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)

The FAH supports the removal of these two measures from the Hospital OQR program, as burden may be reduced with the shift to an electronic clinical quality measure (eCQM).

- Measure Additions
 - COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

This proposed measure would assess the percentage of COVID-19 vaccination coverage in health care personnel providing care in non-long term care facilities (including outpatient hospitals). The FAH supports the intent of this measure but urges CMS to consider postponing its inclusion in the Hospital OQR program until the measure specifications have been finalized and the all of the COVID-19 vaccines currently used under the Emergency Use Authorization have been given full FDA approval. Several factors support this recommendation, including:

- The underlying evidence for this measure is still emerging, as additional vaccines are in development,
- Methods for addressing measure collection challenges related to anticipated “booster” shots may be required,
- Full endorsement by the National Quality Forum (NQF) has not yet occurred, and
- Feedback from feasibility testing is needed to ensure that this measure reflects the most current knowledge and evidence, performs as it was intended, and can be easily collected and reported.

Additionally, this measure would be duplicative at present because CMS already has vaccination status measure for hospitals through HHS's contract with Teletracking. Further, because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions, nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years. Ultimately, the FAH generally believes measures that increase the reporting burden and leverage specifications that are not aligned with other measures should be avoided.

- Breast Screening Recall Rates

CMS proposes to add a new claims-based, facility-level process measure to the Hospital OQR Program for the 2023 payment determination and subsequent years to track the percentage of patients who are recalled after traditional mammography or digital breast tomosynthesis (DBT) screening for additional outpatient imaging. The FAH supports efforts to ensure that breast screening recall rates are within acceptable ranges and appreciates that this new measure addresses the concerns identified with the previous measure (OP-9, Mammography Follow-up Rates). The FAH supports the inclusion of this measure in Hospital OQR once NQF endorsement is received.

The FAH believes that CMS should also explore additional measures to represent a more complete picture of how well facilities are providing timely and appropriate care such as the positive predictive value on screening and diagnostic exams and breast cancer detection rates in women. This set of measures would provide more descriptive information rather than this measure alone.

- ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

CMS proposes to add a new facility-level, electronic process measure to the Hospital OQR Program for the 2023 payment determination and subsequent years to track the percentage of Emergency Department (ED) patients with a diagnosis of STEMI who received timely delivery -- absent contraindications -- of guideline-based reperfusion therapies appropriate for the care setting.

The FAH recognizes the need to address this important clinical area and supports the shift to eQMs. We also appreciate that the measure will likely have achieved NQF endorsement by the time it is implemented in this program. The FAH strongly encourages CMS to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) and complete further evaluations to determine if the measure is reliable and valid across a broader set of EHRs vendors and hospitals rather than the current testing of just two vendor systems. Assessment of how the measure performs using only two systems and two facilities should not be considered sufficient for widespread implementation.

- Modifications to Previously Adopted Measures

- Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)

CMS proposes to return the measure to the OQR measure set for use beginning with the 2023 reporting period/2025 payment determination and subsequent years and to make reporting mandatory for 2023 and all subsequent years. CMS proposes that data submission for all years would be through a CMS web-based tool according to existing policies for the Hospital Quality Reporting (HQR) System (formerly known as the QualityNet Secure Portal).

The FAH supports the return of this measure but encourages CMS to continuously solicit feedback on the implementation and reporting of this measure to ensure that previous concerns relative to data collection burden and inconsistencies of measure scores have been completely addressed.

- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e)

CMS is proposing to restart the use of the OP 37a-e measure beginning with voluntary reporting for the 2023 reporting period/2025 payment determination followed by mandatory reporting for the 2024 reporting period/2026 payment determination and subsequent years. CMS clarifies that hospitals who report voluntarily for 2023 would do so as part of the OQR program rather than the national voluntary program.

The FAH appreciates that CMS provided additional time for hospitals to gain experience with OP 37a-e, but we believe that as with other CAHPS surveys, CMS must expand the modalities by which data are collected to include not only web but also mobile applications. This expansion could reduce the data collection burden while also positively impacting response rates. Analysis of response rates for HCAHPS from 2008 (33%) to 2017 (26%) revealed a percentage change of -22% overall and an average 0.8 percentage point drop per year.¹² CMS must ensure that these erosions in responses do not also occur with this survey. In addition, while this measure has been in use for many years, it has not yet been submitted to NQF for endorsement. NQF endorsement must be achieved prior to mandatory reporting of OP 37a-e.

- Updated OAS CAHPS Reporting Requirements

CMS proposes to add two data collection modes (web-based with either mail or telephone follow-up of non-respondents) for the 2023 reporting period/2025 payment determination and subsequent years to the existing three modes (mail-only, telephone-only, and mixed -- mail with telephone follow-up of non-respondents).

The FAH appreciates the addition of the two additional data collection modes to allow some electronic capture of the survey data but urges CMS to continue to explore additional digital modes including mobile applications.

¹² Federation of American Hospitals. Modernizing the HCAHPS Survey. Released June 2019. Available at: https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_-_Recommendations_from_PELs.pdf.

Electronic Clinical Quality Measure (eCQM) Reporting under the OQR Program

CMS proposes that eCQM technical specifications related to the OQR program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs. Specification updates would generally occur through the Annual Update. eCQM reporting for OQR would be aligned with the Hospital Inpatient Quality Reporting (IQR) Program and the Medicare Promoting Interoperability program for hospitals. CMS invites comment on an alternative eCQM data submission deadline of May 15 (rather than the end of February) to align with OQR measure reporting using the program's web-based tool.

The FAH supports the alignment of the eCQM technical specification updates with the Hospital IQR Program and the Medicare Promoting Interoperability Program for hospitals.

- Hospital OQR Program Validation Requirements

CMS proposes several changes to the Hospital OQR Program data validation process beginning with the 2022 reporting period/2024 payment determination and for subsequent years to further align the data validation process with the Hospital IQR Program. The FAH supports the proposed changes to the OQR data validation process.

- Extraordinary Circumstances Exception (ECE) Policy

CMS proposes to expand the OQR programs ECE policy to cover eCQMs. The FAH supports this proposed expansion.

Request for Comment on Potential Adoption of Future Measures for the Hospital OQR Program

CMS is seeking comments on whether measures can be developed to address transitions of care, particularly as it relates to total hip arthroplasty (THA) and total knee arthroplasty (TKA). The FAH does not support shifting surgical care and eliminating postoperative hospitalization for total joint replacements and similarly complex procedures to hospital outpatient settings due to several issues:

- the gaps in care that arise from inadequate vetting of a patient's functional health status,
- complexity of the procedure,
- the need for postoperative clinical or case management support,
- the need for social/family support following discharge, and
- how these variables may impact anticipated length of stay.

The FAH believes CMS should not seek to develop and implement quality measures for transitions of care for these procedures, as well as cease removing procedures from the newly reinstated – if finalized – Inpatient Only List until the issues listed above are addressed.

Radiation Oncology Model (XVIII.)

Extreme and Uncontrollable Circumstances Policy

CMS is proposing to adopt an Extreme and Uncontrollable Circumstances (EUC) policy for the RO Model. The Agency is proposing to define an EUC as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements and affects the entire region or locale. CMS proposes that if it declares an EUC for a geographic region, then it may 1) amend the model performance period; 2) eliminate or delay certain reporting requirements for RO participants; and 3) amend the RO Model's pricing methodology. In a national, regional, or local event, CMS proposes to apply the EUC policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care.

Furthermore, CMS proposes the following factors for helping identify RO Model participants that are experiencing EUCs, including whether the RO participants are furnishing services within a geographic area considered to be within an "emergency area" during an "emergency period" and whether a state of emergency has been declared in the relevant geographic area. FAH appreciates CMS's consideration of how extreme events can impact RO Model participants' performance and that providers are likely to need model exemptions or modifications.

The spread of the COVID-19 Delta variant is a major risk for health care providers across the country. Implementation of the RO APM beginning on January 1, 2022, places additional stress on radiation therapy providers that are growing increasingly concerned about patient welfare as the Delta variant continues to spread. **We urge CMS to consider expansion of the COVID-19 public health emergency as meeting the criteria for a delay in the implementation date of the RO Model.** Given the continued rise in Delta variant cases, forcing clinics to delay cancer surgeries and other drastic measures, the spread and incidence of COVID has never been worse in many communities, and we are deeply concerned about implementing the RO Model in the midst of our nation's ongoing dire public health emergency. We recommend that CMS leverage the proposed EUC policy to delay the model start date for six months, at a minimum, to allow radiation therapy providers to better prepare for the model while they continue to address the severe and numerous disruptions brought about by the ongoing pandemic, manage growing staffing shortages, and treat patients in this tumultuous time.

RO Model Stop-loss Policy

To align its stop-loss limit policy with the new performance period and proposed baseline period, CMS proposes to modify the stop-loss limit policy such that it applies to RO Model participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation. RO participants that have fewer than 60 episodes in the baseline period do not have sufficient historical volume to calculate a reliable adjustment. Since

these RO participants do not qualify to receive an historical experience adjustment and may see greater increases or reductions as compared to what they were historically paid under fee-for-service (FFS) as a result of not receiving the adjustment, CMS is proposing to use no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the Model. CMS would pay these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS.

While FAH appreciates a stop-loss policy covering losses exceeding 20%, there is still a potentially large and damaging revenue loss for any radiation therapy provider simply because they are seeing a growth in volume over the life of the model. **Variance in efficiency and complexity depending on tumor site limits the effectiveness of a blanket stop loss policy. Facilities with low volume, high acuity patients within a tumor type, such as bone metastasis, brain metastasis, or lymphoma, may choose to refer patients to other facilities for radiation due to the reimbursement risk. The FAH recommends a 20% stop-loss for rate variance per tumor site.** By modifying the stop-loss approach by tumor type, successful programs can expand their services to other tumor types without significant risk due to lower utilization levels.

Beneficiary Cost-sharing for Incomplete Episodes or Duplicate RT Services

Beneficiary cost-sharing rules under FFS Medicare requiring beneficiaries to pay 20 percent also apply to beneficiaries receiving care under the RO Model. CMS outlines an exception to this policy in CMS's RO Model FAQs, question 63, which addresses beneficiary cost sharing for an incomplete episode (due to a beneficiary moving into Medicare Advantage) or a duplicate RT service. CMS's response for this question¹³ describes a complex scenario that calculates beneficiary coinsurance amounts based on copay for FFS amounts, partial FFS amounts, and for RO model amounts. The combinations and scenarios are very likely to be confusing to both patients and to providers alike, and understanding the nuance behind calculating the different coinsurance payments to FFS vs. model amounts based on the situations that may arise through no fault of either the patient or the provider will be extremely challenging. In addition, price transparency has remained a central aim of CMS, and this coinsurance language will likely lead to confusion for both patients and providers. We recommend a modest flat rate payment when the aforementioned events arise within a course of treatment within the model.

RO Model Program Requirements

CMS proposes to accelerate several model requirements, such as CEHRT attestation and reporting of select quality measures, to performance year 1 (PY1) in 2022 for Track 1, instead of the original requirement slated for PY 2 in 2023. The acceleration for meeting these requirements will place additional and unnecessary stress on providers and vendors that planned on an additional year for meeting those program elements. It is unlikely that either providers or vendors will have the capacity to meet these aggressive deadlines given the notice of their acceleration arrived in July of 2021 after the passage of ARPA. **The FAH urges CMS to**

¹³ <https://innovation.cms.gov/media/document/ro-model-faqs-july-2021> No. 63, page 25.

rollback the start date of these model requirements to those start dates established prior to the July update.

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges (XIX.)

Proposal to Increase the Civil Monetary Penalties (Part XIX.B, 45 C.F.R. § 180.90(c))

The FAH continues to be supportive of price transparency initiatives that provide access to clear, accurate, and actionable information, but the FAH strongly opposes the proposed changes to the civil monetary penalty amounts as premature and inappropriate in the midst of the ongoing public health emergency (PHE). Approximately two months after the hospital price transparency final rule was published,¹⁴ the PHE due to COVID-19 began. Despite the extraordinary operational burdens that COVID created, many hospitals nonetheless prioritized good faith compliance with the price transparency regulations, making available the required machine-readable file of standard charges and either an online price estimator tool or consumer-friendly disclosure of shoppable services available on January 1, 2021. Four months later, CMS began working with hospitals to improve compliance, issuing written warning notices to hospitals pursuant to 45 C.F.R. § 180.70(b)(1). To date, CMS has not taken any further enforcement action—it has not requested a corrective action plan from any hospital or imposed a civil monetary penalty on any hospital, despite having such authority under 45 C.F.R. § 180.70(b)(2) and (3).

Based on these limited enforcement efforts undertaken during a national PHE just months after the effective date of the price transparency regulations, it is premature to assess the effectiveness of the existing enforcement authority, let alone understand the reasons for noncompliance and devise appropriate strategies for bolstering compliance. Likewise, the studies cited in the Proposed Rule—which only address initial rates of compliance during periods largely or wholly predating CMS’s issuance of warning notices—cannot do more than speculate as to the effectiveness of enforcement activities that have not yet been deployed.¹⁵ Nonetheless, CMS cites these studies and its early-stage enforcement efforts as creating a concern that there “appears to be a trend towards a high rate of hospital noncompliance.”¹⁶ The FAH does not believe that any such trend could be discerned without data concerning hospitals’ responses to CMS’s educational efforts (including CMS’s August 11, 2021 stakeholder

¹⁴ CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65,524 (Nov. 27, 2019).

¹⁵ 86 Fed. Reg. at 42,313, fn. 410-414.

¹⁶ 86 Fed. Reg. at 42,313.

webinar),¹⁷ written warning notices, corrective action plans, civil monetary penalties, and the publicization of civil monetary penalties. Moreover, further experience with existing enforcement authority would provide valuable information about the types of hospitals that fail to comply with the regulation even in the face of a corrective action or a civil monetary penalty, the causes of such failures (including the extent to which those causes flow from the ongoing PHE), and the appropriate scaling factors (if any) necessary to secure compliance. In short, additional time and experience both during and after the COVID PHE will inform the assessment of whether current enforcement authorities are sufficient and, if not, the identification of appropriate enforcement strategies to secure widespread, good faith compliance.

The FAH is also concerned that the Proposed Rule fails to address any factors that would be considered in determining whether the maximum civil monetary penalty or some lesser amount is appropriate in any individual case. The proposed amendment to 45 C.F.R. § 180.90(c) characterizes the per day penalty amounts as maximums, but the Proposed Rule and regulatory text do not identify the factors that will be considered in imposing a civil monetary penalty in any individual case. In contrast, the HIPAA-related civil monetary penalty regulation cited in the Proposed Rule,¹⁸ includes a number of factors that “the Secretary will consider” in determining the amount of any civil monetary penalty: (a) the nature and extent of the violation, (b) the nature and extent of the resulting harm, (c) the history of prior compliance, (d) the financial condition of the covered entity or business associate, and (e) such other matters as justice may require. Even under the current regulation at 45 C.F.R. § 180.90(c), the FAH believes that the amount of any civil monetary penalty up to the regulatory maximum should take into account the nature, scope, severity, and duration of the noncompliance; the reason for the hospital’s noncompliance including barriers to achieving material compliance; the hospital’s other price transparency efforts; and the financial condition of the hospital.

Proposals to Address Barriers to Accessing the Machine-Readable File (Part XIX.D)

The Proposed Rule indicates that pop-up windows that require a user to agree to terms and conditions in a legal disclaimer before downloading the machine-readable file “do not permit direct access to the file and its contents, and present a barrier.”¹⁹ ***The FAH strongly opposes expanding the accessibility requirements at 45 C.F.R. § 180.50(d)(2) to prohibit the use of pop-up windows containing critical information and disclaimers for acknowledgment by the consumer.*** On its own, a machine-readable file of standard charges and rates can be confusing or even misleading to consumers if presented without any context or explanation. For example, an uninsured patient may not understand that the discounted cash prices shown in the machine-readable file do not reflect charity care and other financial assistance programs or be aware of the availability of financial counselors who can provide individualized information on public coverage options (*e.g.*, Medicaid and CHIP) and eligibility for the hospital’s financial assistance

¹⁷ August 11, 2021 Hospital Price Transparency Stakeholder Webinar Presentation, <https://www.cms.gov/files/document/august-11-2021-hospital-price-transparency-odf-slide-presentation.pdf>.

¹⁸ 86 Fed. Reg. 42,315 (citing 45 C.F.R. § 160.404)

¹⁹ 86 Fed. Reg. 42,319.

programs. Other patients may not understand that a particular hospital does not employ physicians or other billing professionals, and thus the machine-readable file only reflects standard charges and rates for facility services. And when a machine-readable file presents case rate data for one payer and per diem rate data for a second payer for the same service, patients may not understand the differences in payment methodology and that the lower per diem rate might actually result in higher cost-sharing liability than the higher case rate. CMS previously recognized the importance of appropriate disclaimers when it “encourage[d] . . . hospitals [to] provide appropriate disclaimers in their price estimator tools, including acknowledging the limitation of the estimation and advising the user to consult, as applicable, with his or her health insurer to confirm individual payment responsibilities and remaining deductible balances.”²⁰

Disclosing this and other information is critical to reducing the very real risk of consumer confusion of a contextless machine-readable file of standard charges and rates, and hospitals should be encouraged rather than dissuaded from providing these disclaimers. Such disclaimers can be and often are presented in the form of an acknowledgment rather than terms and conditions or an agreement, and the FAH believes that hospitals can properly require that a consumer acknowledge the hospital’s disclaimers without compromising the accessibility of the machine-readable file.

Clarification of Price Estimator Tool Requirements (Part XIX.E.1)

The FAH opposes any requirement or clarification that an online price-estimator tool must employ a standard-charges-based methodology to provide an estimate of a patient’s expected cost-sharing obligation for an item or service because it unduly limits hospital flexibility without benefitting consumers. The hospital price transparency regulations state that a hospital is deemed to comply with the requirement to display shoppable services in a consumer-friendly manner if the hospital maintains “an internet-based price estimator tool” that provides “estimates” for a sufficient number of shoppable services, allows consumers to obtain a real-time “estimate” of their cost-sharing obligations, and is prominently displayed and accessible.²¹ The regulation appropriately contains no language limiting the methodology used by the hospital to produce the required “estimate” through the online price-estimator tool and does not require the tool to disclose the “standard charges” or crosswalk to the machine-readable file of standard charges. The online price-estimator provision thus properly provided hospitals and their vendors to develop their own methodologies for producing these estimates. For example, a hospital might determine that past remittance advices from a payer provide a more reliable basis for determining the total anticipated allowed amount as compared to using standardized charges to determine the anticipated allowed amount because past remittance advice data can be used in a manner that accounts for typical circumstances (*e.g.*, the typical length of stay for a stay paid on a per diem methodology) and excludes outliers. Moreover, the availability of the machine-readable file ensures that a consumer that is interested in considering both the hospital’s estimate of his or her cost-sharing obligation and the payer-specific negotiated rates will be able to access both pieces of information.

²⁰ 84 Fed. Reg. at 65,579.

²¹ 42 C.F.R. § 180.60(a)(2).

The FAH is also concerned about the significant burdens on hospitals if the online price estimator tool requirements were changed to prescribe or limit the methodologies used to develop price estimates. The FAH’s members have made considerable investments in the development of online price-estimator tools, both before and following the promulgation of the hospital price transparency regulations. Any required methodological changes—particularly those that alter the primary data sources used to develop the estimates—would impose significant costs and burdens on these hospitals that have prioritized both price transparency and compliance with the price transparency regulations promulgated by CMS without any data indicating that such methodological changes improve the reliability of estimates or otherwise benefit consumers. Therefore, the FAH opposes any requirement—whether described as a clarification or a change in policy—that a price estimator tool must use a standard-charges-based methodology in order to satisfy the consumer-friendly disclosure requirement under 42 C.F.R. § 180.60(a)(2).

In addition, ***the FAH opposes any change to the price-estimator tool regulation limiting disclaimers that provide consumers with information about the inherent limitations of the estimate.*** The Proposed Rule expresses concern with disclaimers that “indicate that the price is not what the hospital anticipates that the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances.” But when a hospital provides an estimate of the amount the hospital anticipates the patient will pay for the shoppable service—based on the information available and any reasonable assumptions about typical cases—it should be encouraged to explain to the consumer the limitations of the estimate in typical cases as well as unusual or unforeseeable circumstances. For example, if a particular procedure is paid on a per diem basis, the estimate provided will inherently assume a particular length of stay, which could reasonably be based on the average or median length of stay. It would be neither unusual nor unforeseeable that an individual patient would have a length of stay that is longer or shorter than that average or median length of stay used for the estimate, and it would be appropriate for a hospital to note that the patient’s cost-sharing obligation will vary based on his or her actual length of stay. ***In short, the patient’s actual cost-sharing liability varies based on a range of typical and foreseeable factors that are unknown or unknowable at the time of any price estimate, and the disclosure of this information to consumers should be encouraged rather than discouraged.*** In fact, CMS noted as much in the price transparency final rule, when it “encourage[d] . . . hospitals [to] provide appropriate disclaimers in their price estimator tools, including acknowledging the limitation of the estimation.”

Standardization of the Machine-Readable File (Part XIX.E.4)

The Proposed Rule also request comments regarding improving the standardization of the machine-readable file. ***The FAH strongly urges the Secretary to exempt from any standardization requirements those hospitals that made public a machine-readable file of standardized charges prior to the adoption of standardization requirements.*** Failing to offer such an exemption would result in the standardization efforts operating as a tax or penalty on those hospitals that invested in and prioritized good faith compliance with the machine-readable file requirement because these hospitals—having already incurred significant expense to comply with the law—would face the additional expense of re-engineering (rather than merely updating)

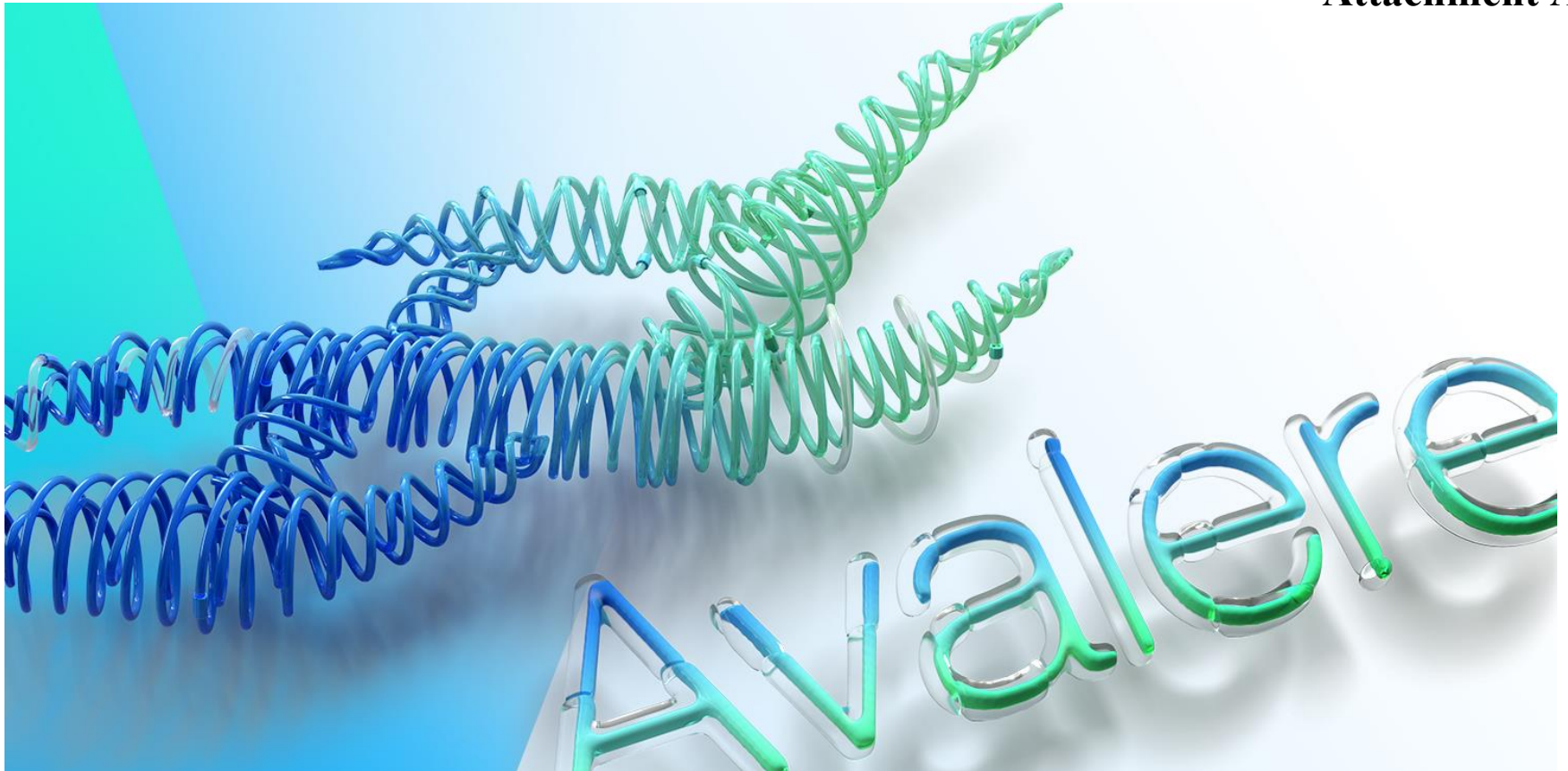
the machine-readable file. In other words, standardization without such an exemption would implicitly and inappropriately reward hospitals that delayed compliance efforts.

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or any member of my staff at 202-624-1500.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Kuntz". The signature is fluid and cursive, with a large, stylized initial "A" and "M".

Enclosure: Attachment A



OPPS Medicare Part B Payment Impact Analysis

Avalere Health | An Inovalon Company
March 2021

This analysis was funded by the Federation of American Hospitals. Avalere maintained full editorial control.

Executive Summary

1

Certain hospitals are eligible for and participate in the 340B Drug Pricing Program, which is administered by HRSA and allows entities to purchase outpatient drugs at a discount – approximately 34%, on average¹.

2

Beginning in CY 2018², CMS has reduced payment to hospitals for separately payable drugs purchased under the 340B Program by 28.5% to lower beneficiary copay and improve Medicare program's efficiency and equity.

- Estimated \$1.6B in reduced drug payments were reallocated to increase OPPS payment rates by 3.2% to all hospitals for non-drug items and services.
-

3

Key Findings from the analysis estimating the impact of reverting back to the CY 2017 OPPS payment policy:

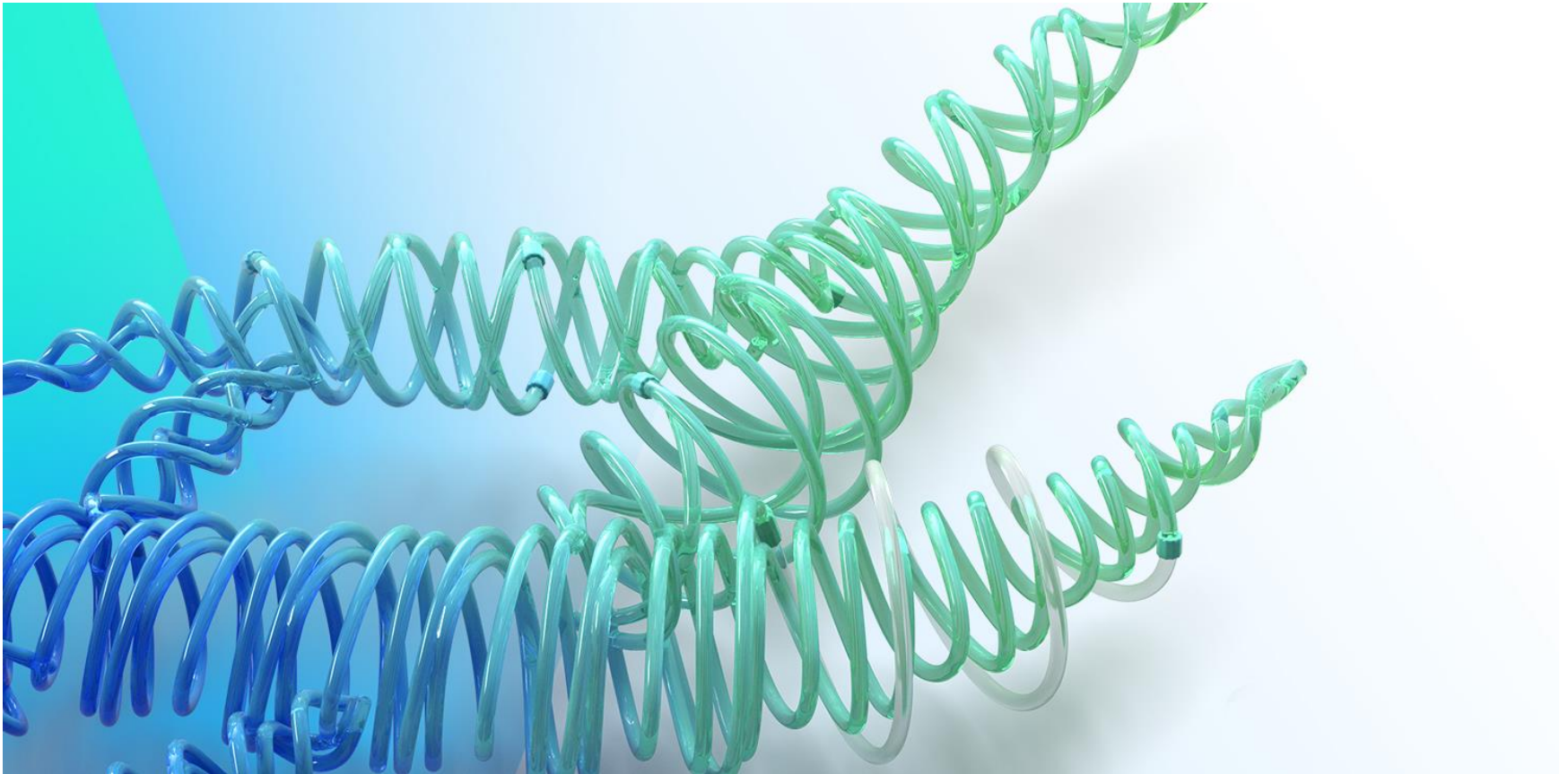
- Beneficiary cost-sharing for separately payable drugs at 340B OPPS hospitals would increase by \$472.8 million.
- 82% of all OPPS hospitals would see net total payment decreases:
 - 89% of rural hospitals and 80% of urban hospitals
 - 49% of 340B hospitals

HRSA: Health Resources and Services Administration; CMS: Centers for Medicare & Medicaid Services; OPPS: Outpatient Prospective Payment System;

1. [MedPAC's Report to the Congress](#): Medicare Payment Policy, March 2016, Chapter 3

2. CMS. "Calendar Year 2018 Outpatient Prospective Payment System and Ambulatory Surgical Center [final rule](#)," November 2017





Background on OPSS Payment Adjustment

HRSA and CMS Operate Different Programs, with Different Purposes

1

HRSA operates the 340B Program which allows certain qualifying hospitals and other entity types to purchase outpatient drugs from manufacturers at a discount

- As reported in MedPAC's March 2016 Report to Congress, OIG estimated the average 340B discount to be approximately 34%¹
 - According to HRSA, 340B discounts range from 25% to 50% of the cost of the drugs²
-

2

CMS uses the outpatient prospective payment system (OPPS) to reimburse for Medicare-covered outpatient hospital services and pay separately for certain drugs that are administered during an outpatient hospital visit.

3

OPPS payment change to the Medicare reimbursement rate for drugs purchased under the 340B Program does not impact the discount amount that hospitals receive from manufacturers.

The OPPS Rule Reduces Cost-Sharing and Medicare Payments for Part B Drugs Purchased Under 340B

- The CY 2018 OPPS final rule and subsequent annual rules, including the finalized CY 2021 rule, adjust Part B payments to all separately payable, non-pass-through Part B drugs (excluding vaccines) purchased through the 340B Program.
- CMS cited patient copayments, increased number of 340B covered entities, and rise of Part B drug prices as reasons for the payment change.

Payment Change

Previous | ASP + 6%*

↓ 28.5 Percentage Point Reduction

Current
OPPS Rule | ASP – 22.5%*

Reporting Requirements



CMS established modifiers for facilities to report any separately payable drugs acquired under 340B

 **Initially, CMS estimated the OPPS payments for separately payable drugs, including beneficiary cost-sharing, would decrease by \$1.6 billion, with a corresponding increase in payments for non-drug services by 3.19% for all hospitals.**

OPPS: Outpatient Prospective Payment System; ASP: Average Sales Price; CMS: Centers for Medicare & Medicaid Services

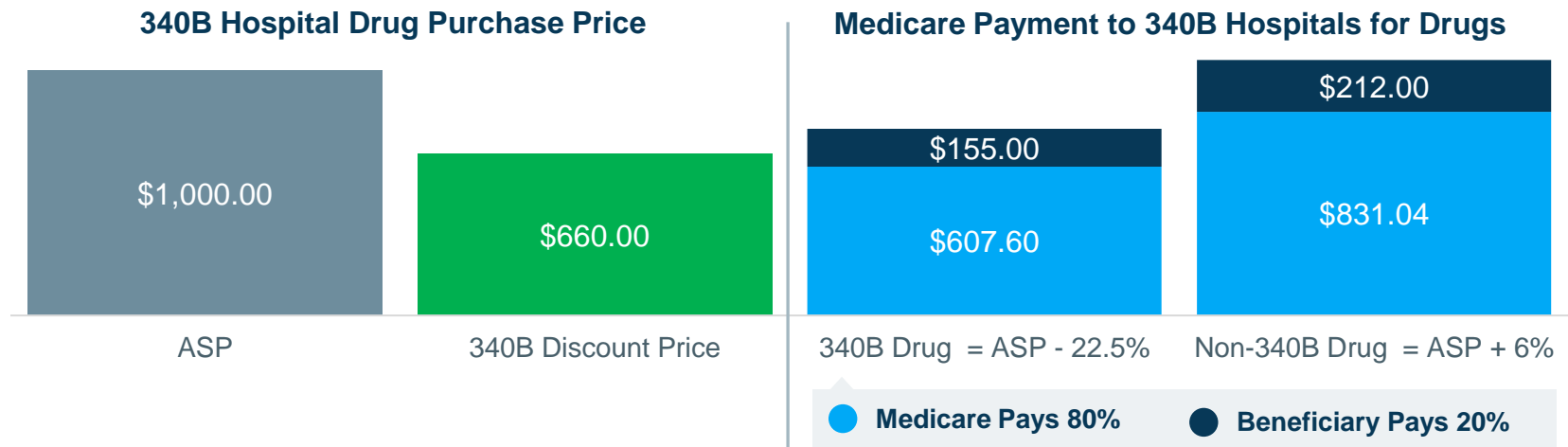
*Avalere analysis reflects the impact of budget sequestration of 2013, which reduced the Part B drug add-on payment from ASP + 6% to ASP + 4.3% and for 340B-purchased drugs from ASP - 22.5% to ASP - 23.7%. Of note, sequestration has been temporarily lifted due to the public health emergency.

Source: Centers for Medicare & Medicaid Services. "Calendar Year 2018 Outpatient Prospective Payment System and Ambulatory Surgical Center [final rule](#)," November 2017



Illustration of Medicare's OPPS Payment for Separately Payable Drugs and Impact on Beneficiary Copayments

- Current OPPS payment policy involves different reimbursement rates for separately payable drugs based on whether the hospital purchases the drug under the 340B Program.
- Hospitals that participate in the 340B Program can purchase outpatient drugs at a discount – approximately 34%, on average, but the discount range varies among facilities and drugs¹.

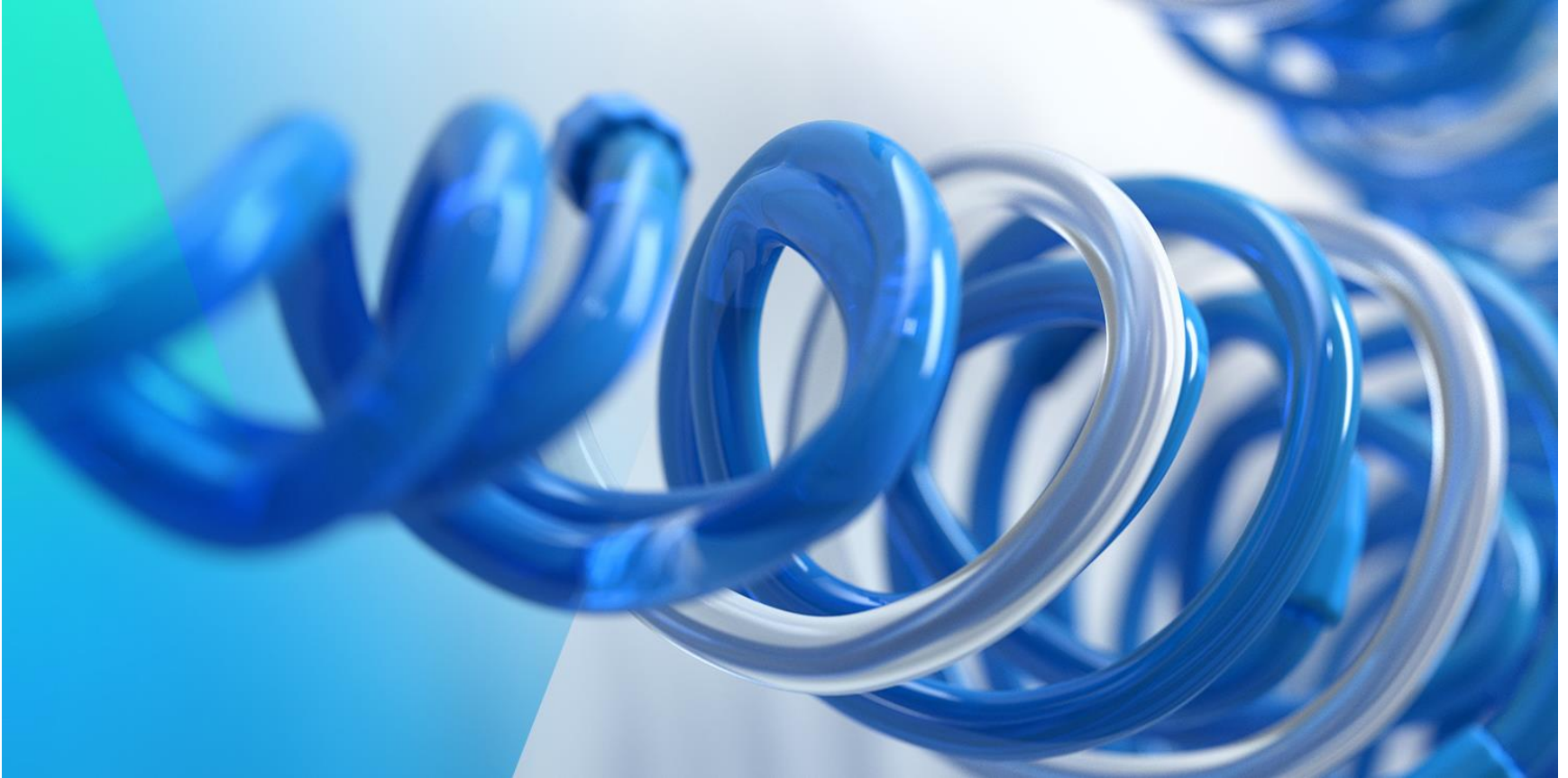


Reversing 340B payment policy would increase beneficiary cost-sharing by 37% for 340B drugs.

ASP: Average Sales Price

Note: Example is illustrative only. 340B discount price reflects 34% of the ASP. The ASP-based payment is split to reflect the beneficiary paying 20% and Medicare paying 80% of drug cost. Medicare payment is adjusted to represent a 2% reduction due to the sequester (currently suspended due to public health emergency). Beneficiary coinsurance is not impacted by the sequester. The amounts shown only reflect payments for a drug and do not account for premiums or other payments.

1. [MedPAC's Report to the Congress](#): Medicare Payment Policy, March 2016, Chapter 3



Net Impact of the OPPS Policy Reversal

Overall Analytic Approach

To better understand the overall impact associated with a reversal of the current OPPS payment policy, Avalere modeled changes to Part B drug and services spending.

In this analysis, Avalere:

Identified Medicare Part B drug payments using 2019 claims data, separating drug payments for 340B and non-340B purchased drugs

Projected 2021 Part B payments for drugs and services under the current policy, using CMS' total payment estimates from the CY 2021 OPPS rule impact file*

Simulated payment changes for drugs and services under the policy reversal and return to the ASP + 6.0% methodology for 340B drugs**

Estimated net impact on total OPPS payments

Stratified data and results to demonstrate impact on specific subsets of hospitals

Note: See Appendix for full description of methodology

* CY2021 OPPS Final Rule Impact [File](#)

**The budget sequestration of 2013 reduced the Part B add-on payment to 4.3%; the sequester also further reduced the 340B drug payment rate from -22.5% to -23.7%. Of note, Avalere did not model the temporarily suspension of the sequestration due to the public health emergency.



Nearly 90% of Rural OPPS Hospitals Would See Decrease in Net Payments Under OPPS Payment Policy Reversal

Approximately 82% of all OPPS hospitals would see a reduction in net payments as a result of a 340B drug payment policy reversal

1 All rural sole community and essential access hospitals would see a reduction in net OPPS payments as a result of reversing the policy.

2 83% of rural OPPS hospitals in the analysis are not subject to 340B drug payment cut and they have benefited from the OPPS redistribution effects resulting from the increase in base payment rates for non-drug items and services.

Impact of the OPPS Payment Change on All Hospitals, Stratified by Rural vs. Urban

Hospital Type	Total Hospitals	Number of Hospitals Estimated to See Decrease in Net Payment	Percentage of Hospitals Estimated to See Decrease in Net Payment
Rural	725	644	88.8%
Sole community and essential access	427	427	100.0%
Urban	2,729	2,184	80.0%
Total	3,454	2,828	81.9%



Under a Policy Reversal, Half of 340B Hospitals Would See a Net Payment Decrease in Total OPPS Payments

77% of rural OPPS 340B hospitals would see a net decrease in total OPPS payments

Impact of the OPPS Payment Change on 340B Hospitals*, Stratified by Rural vs. Urban			
Hospital Type	Total Hospitals	Number of Hospitals Estimated to See Decrease in Net Payment	Percentage of Hospitals Estimated to See Decrease in Net Payment
Rural	356	275	77.2%
Urban	876	334	38.1%
Total	1,232	609	49.4%

- While OPPS 340B hospitals would see an increase in drug payments under a policy reversal, for 49.4% of those hospitals the corresponding budget neutrality payment reduction for all non-drug items and services outweighs the drug payment increase.
- Across all OPPS 340B hospitals in the country, the aggregate beneficiary cost-sharing amount for separately payable drugs is estimated to increase by \$472.8 million under a policy reversal.

* Rural sole community hospitals and essential access hospitals have been excluded from the 340B drug payment rate reduction under OPPS and continue to be reimbursed at ASP + 6%.

Policy Reversal Could Impact Hospitals' Ability to Serve Low-Income Patients

Uncompensated care rates are comparable at 340B and non-340B hospitals

Uncompensated Care Rate /

Hospital Type	Total Hospitals*	Weighted Average of Uncompensated Care as % of Total Operating Costs
All 340B Hospitals**	1,231	4.2%
Non-340B Hospitals, Acute Care only***	1,757	4.4%

OPPS: Outpatient Prospective Payment System;

* Hospitals with data available for calculation of the uncompensated care metric.

** Enrolled in the 340B program as of February 2021.

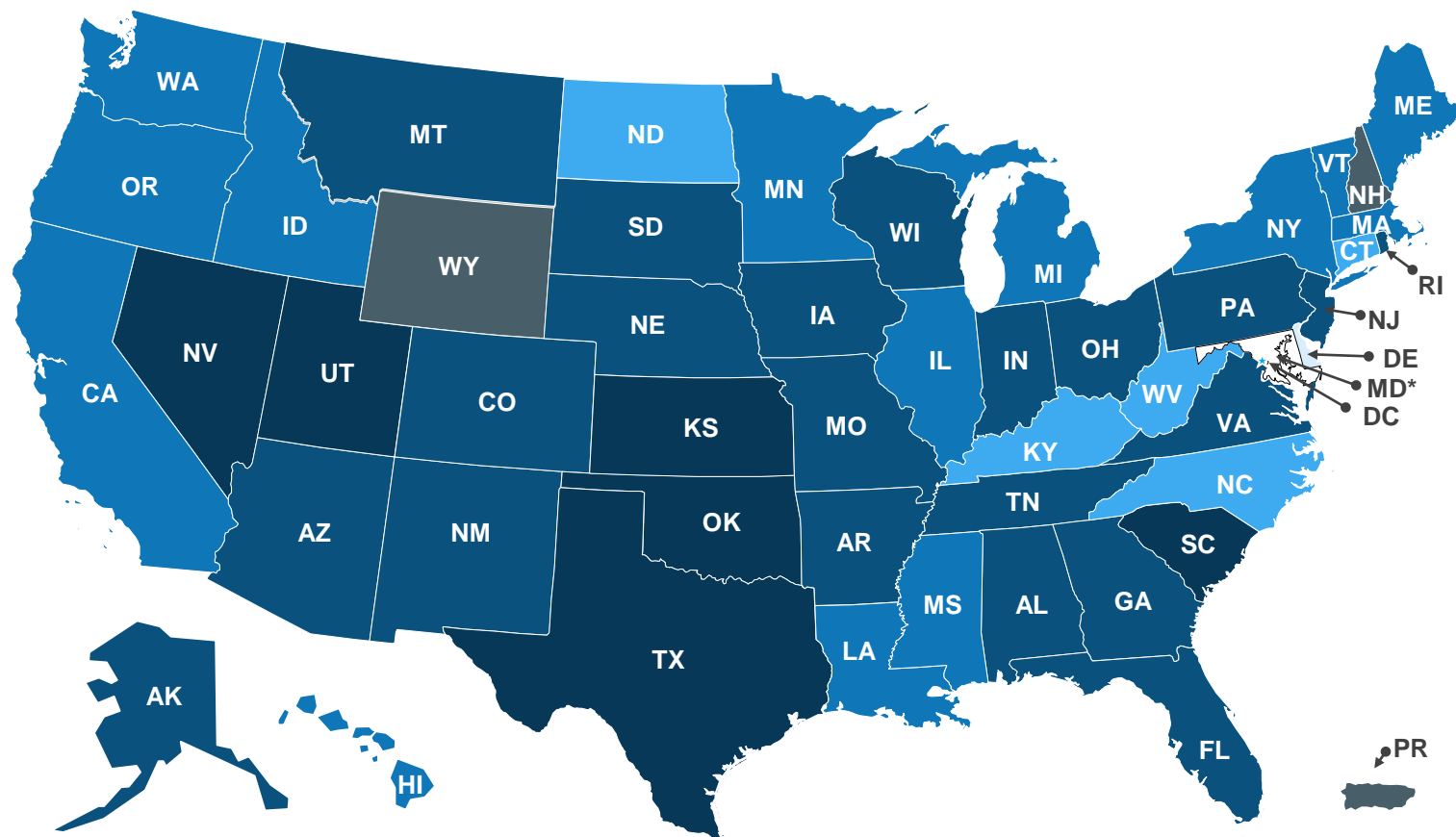
*** 451 non-acute care hospitals i.e., psychiatric, rehabilitation and long-term care are not captured since they largely do not report uncompensated care costs.

Source: Avalere analysis of FY 2018 Medicare cost report data.



82% of All OPPS Hospitals Would See a Reduction in Net Total OPPS Payments

Percentage of all OPPS hospitals with decrease in net total OPPS payments in each state



Share of Hospitals with Decreased Net Total OPPS Payments

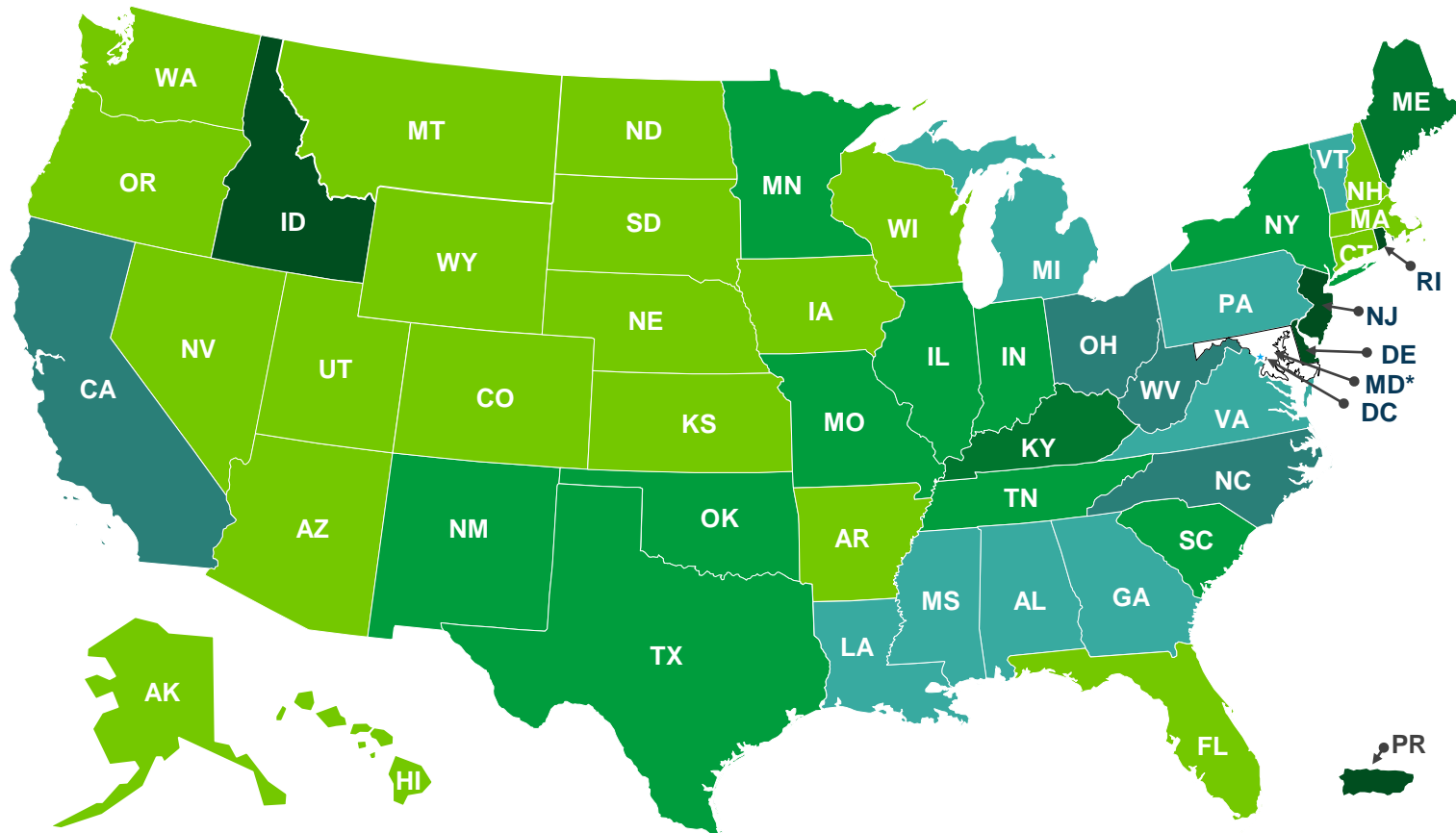
<50% 50-59% 60-69% 70-79% 80-89% 90-99% 100%

Note: Hospitals in MD are not paid under OPSS methodology and excluded from the analysis.



89% of Rural OPPS Hospitals Would See a Reduction in Net Total OPPS Payments; 100% in 21 States

Percentage of rural OPPS hospitals with decrease in net total OPPS payments in each state

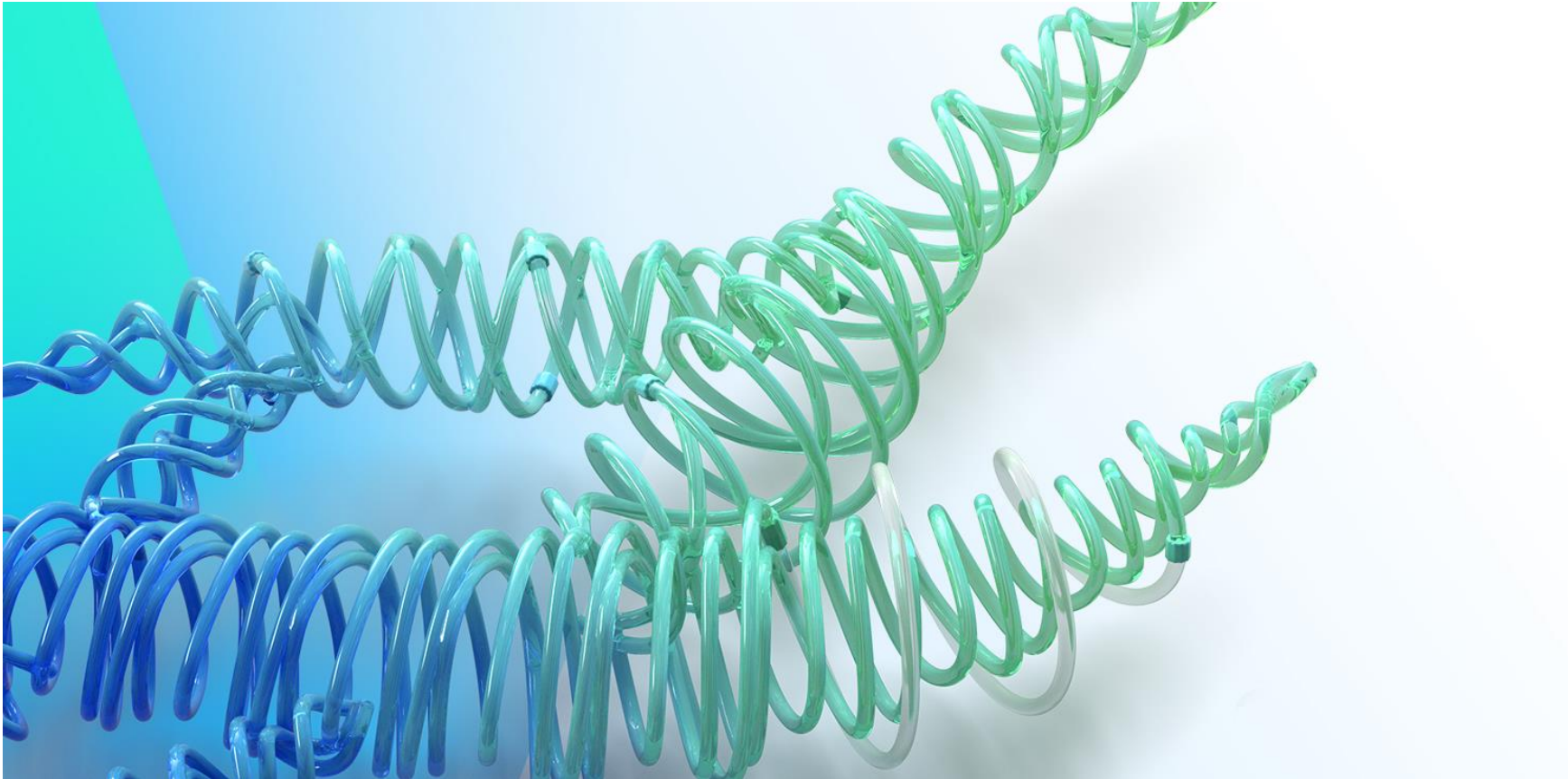


Share of Hospitals with Decreased Net Total OPPS Payments

0% 60-69% 70-79% 80-89% 90-99% 100%

Note: Hospitals in MD are not paid under OPSS methodology and excluded from the analysis. Also, there were no rural hospitals identified in DC, DE, NJ, RI, and PR, therefore the share of hospitals with decrease in payments is 0%.





Appendix

Methodology

Part B Drug Selection: Avalere analyzed 2019 Medicare Standard Analytical File that includes 100% of fee-for-service claims from hospital outpatient departments, the most recent data available.

- Avalere captured all drugs included in the quarterly 2019-2020 ASP Drug Pricing Files¹
- Vaccines/Numerical codes: Avalere excluded vaccines per OPSS rule

Part B Drug Spending: Avalere identified total Medicare reimbursement for Part B drugs (government and beneficiary portion), separating between non-340B and 340B volume as indicated on claims by non-pass-through status indicator “K” and modifiers “JG” and “TB” for the latter. Avalere projected 2019 claims-based drug reimbursement using the ~4% average change in OPSS payment rates for separately payable drugs based on Addendum B data from 2019, 2020 and 2021 rules.

Hospital Selection: Analysis captures 3,454 hospitals paid under OPSS and included in the final rule’s Impact File.² To prevent overstating the impact of a policy reversal, the analysis excludes 104 hospitals that did not participate in 340B in 2019 but are participating in the program as of February 2021 and meet criteria for the reduced drug payments in 2021.

Of note, the final rule’s Impact File does not include 340B-eligible children’s and free-standing cancer hospitals that receive proportional adjustments to their OPSS payment rates. Similarly, critical access hospitals and hospitals located in Maryland are eligible for 340B prices but not paid under OPSS.

340B Participation: Avalere assessed current (as of February 2021) hospital 340B participation using the 340B Office of Pharmacy Affairs information System.

Total OPSS Net Payment Impact: Avalere used the CMS-estimated hospital-level total OPSS payments for CY2021 as a baseline² to model the impact of the policy reversal that captures both the 340B drug payment increase back to ASP+6% for impacted hospitals and the reduction in annual base rate updates implemented back in 2018 for budget neutrality. For a subset of 227 hospitals that were subject to the reduced payment rate in 2019 but are no longer 340B as of February 2021, Avalere modeled their baseline 2021 drug payments to reflect ASP+6%.

¹ ASP Drug Pricing [Files](#)

² CY2021 OPSS Final Rule Impact [File](#)

