NORTON ROSE FULBRIGHT

Health Law Check-Up

A quarterly newsletter from the healthcare team at Norton Rose Fulbright

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To our clients and friends:

Welcome to the inaugural edition of the Health Law Check-Up, the new quarterly newsletter produced by Norton Rose Fulbright's healthcare team. We know that staying up-to-date on changing regulations, industry trends, and precedent-setting cases is vital, but that your time is limited now more than ever. Our goal with this newsletter is to supplement our Health Law Pulse blog and monthly webinar series with an opportunity to take a closer look at topics of importance to the healthcare industry in a format that you can read anywhere, whether you print it and go or download to your e-reader.

This quarter's edition has a heavy focus on regulatory topics, including the recently issued Stark and AKS Final Rules, along with telehealth, behavioral health and data privacy. In future editions, we expect to cover academic medical center issues, government investigations and compliance, and international healthcare.

As always, we would love to hear from you on how you are liking the newsletter and future topics you would like to see covered.

Stay well and have an enjoyable holiday season.

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A deeper dive into the new Stark Law and AKS Final Rules

by Jeff Wurzburg, Joseph Keillor, Mary Ytterberg, Elise LeGros and Hayley White

In what is likely the most substantial fraud and abuse rulemaking in over a decade, the U.S. Department of Health and Human Services Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS) published on November 20, 2020, long-awaited final rules changing the regulations addressing the Anti-Kickback Statute (AKS) and Civil Monetary Penalties for Beneficiary Inducements (CMP), and the Physician Self-Referral Law (the Stark Law), respectively. Both rules were part of the HHS Regulatory Sprint to Coordinated Care and are the culmination of a multi-year effort that began with CMS and OIG issuing requests for information in September 2018 and issuing proposed rules in October 2019 (as discussed in prior *Health Law Pulse* blog posts here and here). In a press release accompanying the final rules, HHS Secretary Alex Azar touted the final rules as "regulatory reforms [that] will mean better care, including innovative arrangements with digital technology that may help patients receive care during the COVID-19 pandemic." The coordinated effort between different operating divisions of the U.S. Department of Health and Human Services is notable in its breadth and highlights the importance of these policy changes towards the goal of removing barriers to coordinated care that aims to reduce cost and improve quality.

Value-based rules

Perhaps the most critical part of the final rules is a new three-tiered Stark Law exception for value-based arrangements and three similar but non-identical AKS safe harbors.

Stark Law value-based exception

In finalizing the new exception, CMS touts that it boldly "depart[s] from the historic exceptions to the [Stark Law] in order to facilitate the transition to a value-based health care delivery and payment system." The three tiers of the exception are based on the level of risk being borne by the parties to the arrangement, i.e., full financial risk, meaningful downside financial risk (softened in the final rule to a 10 percent threshold from the proposed rule's 25 percent threshold), and care coordination arrangements with no or lower risk. Greater flexibility is provided for higher-risk arrangements on the assumption that such arrangements inherently have disincentives to at least partially curb overutilization.

The value-based arrangements exception is built on a series of interwoven definitions such as "value-based activity," "value-based arrangement," "value-based enterprise (VBE)," "value-based purpose," "VBE participant," and "target patient population." The definitions are necessarily formal as CMS and OIG strived to capture a broad universe of potential arrangements between varied types of parties. However, if one imagined a physician-hospital arrangement in which the hospital incentivized a physician group to enhance the quality of care to surgical patients, including through the postoperative phase, with a goal of improving outcomes such as reducing readmissions, the "value-based enterprise" would simply be the miniature 'network' of the hospital and the physician group (as governed by the contract between the parties), the "value-based purpose" would be to improve the quality of care to surgical patients, and the "value-based activity" could be the physicians group's efforts to develop and adhere to redesigned care protocols. Under this new exception, the parties would have greater flexibility in structuring the compensation payable to the physician group, as, for example, the parties would not need to satisfy — at least for Stark Law purposes — the element of 'fair market value,' which does not always cleanly fit into the value-based context.

The final rule was largely consistent with the proposed rule, resulting in an exception that should be fairly flexible. For example, the proposed rule floated the possibility of tightening the proposed definition of "VBE participant" to exclude laboratories, DMEPOS suppliers, and various pharmaceutical-related parties such as manufacturers and benefit managers, but the final rule refrained from excluding specific types of suppliers. However, in the final rule, for arrangements below the meaningful downside risk threshold, (i) CMS added a "commercially reasonable" element and (ii) was more prescriptive regarding active monitoring of whether an arrangement is in fact furthering its value-based purpose(s), with express requirements to promptly amend or terminate arrangements that are not found to be furthering their value-based purpose(s). The table below summarizes the elements applicable to each tier of the exception.

Element	Full risk	Meaningful downside risk	Value-based
No inducement to reduce medically necessary items/services; remuneration is for value-based activities undertaken for the target patient population,* standard limitations on required referrals; 6 year record-keeping requirement	Yes	Yes	Yes (* with express monitoring requirement)
Any performance/quality standards must be written, objective/ measurable, with only prospective changes	No	No express element	Yes
Set in advance requirement	No	Yes	Yes
Signed writing requirement	Very limited	Limited	Yes
Commercially reasonable requirement	No	No	Yes
Volume/value of referral or other business generated prohibition	No	No	No
Fair market value requirement	No	No	No

AKS value-based safe harbors

The OIG finalized three value-based safe harbors designed on a sliding scale like the similar Stark exception, in that the more significant the financial risk undertaken by the participants, the greater the flexibility provided by the AKS safe harbors. The OIG states that "[a]n overarching goal of our proposals was to develop final rules that protect low-risk, beneficial arrangements without opening the door to fraudulent or abusive conduct that increases Federal health care program costs or compromises quality of care for patients or patient choice."

The OIG and CMS underscored that there are some differences between the Stark Law's value-based arrangements exception and the corresponding AKS safe harbors promulgated in the OIG's final rule, even if the basic definitional framework is quite similar. The OIG noted their intent to align value-based termination and safe harbor conditions with those being finalized by CMS, but noted that "complete alignment is not feasible because of fundamental differences in statutory structures and sanctions across the two laws." Additionally, the OIG states that the AKS final rule is intended to "provide 'backstop' protection for Federal health care programs and beneficiaries against abusive arrangements that involve the exchange of remuneration intended to induce or reward referrals under arrangements that could potentially satisfy the requirements of an exception to the physician self-referral law."

All three safe harbors protect in-kind remuneration, but — in a key departure from the corresponding Stark Law exception — monetary remuneration is only protected under the substantial downside financial risk and full financial risk safe harbors. The three value-based safe harbors are as follows:

- **Care coordination arrangements to improve quality, health outcomes and efficiency.** This safe harbor applies to VBE participants that have little or no financial risk and it only protects in-kind remuneration. In order to meet the safe harbor, the value-based arrangement must take on at least one evidence-based outcome measure. The parties must establish legitimate outcome or process measures that the parties reasonably anticipate will advance the "coordination and management of care for the target patient population based on clinical evidence or credible medical or health science

support." The arrangement must be commercially reasonable and the offeror of the remuneration may not take into account the volume or value of, or condition the remuneration on "(i) referrals of patients that are not part of the value-based arrangement's target patient population; or (ii) business not covered under the value-based arrangement." The recipient of remuneration must contribute at least fifteen percent of the offer's cost or the FMV of the in-kind remuneration.

- **Value-based arrangements with substantial downside risk.** This safe harbor protects in-kind and monetary remuneration between VBEs and VBE participants. Many of the safe harbor's elements align with the Care Coordination safe harbor but also requires substantial downside financial risk for at least one year. VBE participants are required to "meaningfully share" in downside, meaning at least five percent of the losses and savings (OIG had proposed eight percent). The shared savings and losses threshold is reduced in the final rule to thirty percent, from the forty percent threshold that was proposed. A twenty percent threshold is required for clinical episodes of care.
- **Value-based arrangements with full financial risk.** This safe harbor covers monetary and in-kind remuneration between a VBE and VBE participant. In order to have full financial risk, "the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least one year."

Throughout the final rule, the OIG states that they have placed "guardrails" to "prevent fraud and abuse under the guise of a value-based arrangement." Similarly, the OIG reiterates the longstanding principle that failing to meet a safe harbor does not make an arrangement unlawful. Instead, "[a]rrangements that do not fit in a safe harbor are analyzed for compliance with the Federal anti-kickback statute based on the totality of their facts and circumstances, including the intent of the parties."

The final rule permits, in a change from the proposed rule, any type of actor to be a value-based participant (VBP). However, despite their ability to participate as a VBP, these entities are ineligible to use the value-based safe harbors to protect remuneration: pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices or medical supplies; entities or individuals that sell or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and medical device distributors and wholesalers. The final rule acknowledges that digital health can play an important role in care coordination. The OIG creates a special pathway for medical device manufacturers and medical supply and DMEPOS companies to be eligible under the care coordination arrangements safe harbor. The entities are considered "limited technology participants" under the final rule.

Therefore, while the OIG creates a wider umbrella for entities to participate in VBEs, it will be critical to track remuneration between these entities and the VBE/VBE participants because certain remuneration will not be protected under the safe harbor.

Element	Full risk	Meaningful downside risk	Care-coordination
In-kind contributions only	No	No	Yes
Legitimate and verifiable criteria	No	No	Yes
Set in advance requirement	No	Yes	Yes
Signed writing requirement?	Yes	Yes	Yes
Commercially reasonable requirement	No	No	Yes
Volume/value of referral or other business generated prohibition?	Yes	Yes	Yes
Applies to Participant-Participant Arrangements?	No	No	Yes
Evidence of compliance to HHS (upon request)	Yes	Yes	Yes

Other Stark Law changes

The Stark Law final rule also included numerous additional changes beyond the value-based arrangement exception, including various definitional changes, clarifications, liberalizations, and a pair of additional new exceptions.

Definitional changes

- **Commercially reasonable.** One of the more critical definitional changes is that CMS added a definition for "commercially reasonable," whereas previously it had only briefly addressed the concept of "commercially reasonable," primarily in its preamble to the 1998 proposed rule. Under the new definition, commercially reasonable "means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." CMS noted in commentary that the "key question" to this analysis is "whether the arrangement makes sense as a means to accomplish the parties' goals." CMS gave a non-exhaustive list of examples of when an arrangement may be commercially reasonable yet not profitable, including arrangements for "community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under [EMTALA], the provision of charity care, and the improvement of quality and health outcomes."
- **Fair market value.** CMS also revised and restructured the definitions for "fair market value" and "general market value." In the commentary describing these changes, CMS made helpful comments with respect to permissible compensation arrangements. CMS recognized that the fair market value of a transaction may not always coincide with published salary surveys. Some examples given by CMS included that a hospital might legitimately pay a salary higher than what published surveys indicate for the typical orthopedic surgeon in that hospital's location in securing the services of one of the top orthopedic surgeons in the country, and that a higher-than-typical salary may be needed to attract a cardiothoracic surgeon to an area that currently has no cardiothoracic surgeons. CMS also acknowledged that while an entity's compensation of a physician at an ongoing loss may present concerns, there also may be valid reasons for entering into such an arrangement.
- **Isolated financial transaction.** The definition of isolated financial transaction was also revised and restructured to expressly foreclose aggressive uses of the corresponding exception relating to making a lump-sum payment for services previously provided over a period of time and not previously compensated. However, changes to the writing requirement and the new exception relating to "limited remuneration to a physician" will in some cases help blunt the impact of this tightened definition.
- **Designated health services.** CMS also revised the definition of designated health services (DHS) to include that with respect to services furnished to inpatients by a hospital, a service is not considered a designated health service payable by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to hospital under any of the following prospective payment systems (PPS): Acute Care Hospital Inpatient, Inpatient Rehabilitation Facility, Inpatient Psychiatric Facility, or Long-Term Care Hospital. Thus, for example, if the ordering of an MRI by a specialist for a hospital inpatient does not change the payment to the hospital based on the MS-DRG assigned upon admission of the patient to the hospital, then the MRI referral would not be for DHS. From a practical perspective, we expect that the revision may be more likely to affect an overpayment analysis on a retrospective basis than it would alleviate compliance obligations (e.g., contracting) on a go-forward basis, as we expect that it would likely be difficult to anticipate prior to the referral whether any referral would cause a prospective payment to increase. Upon learning that a hospital has a financial arrangement with a physician who refers to the hospital and the arrangement does not meet a Stark exception, if that physician was not the one to order the inpatient hospital admission, the revised definition of DHS may operate to reduce the amount that needs to be refunded, as now the hospital can isolate payments only for DHS referrals by the physician that resulted in an increase over the expected MS-DRG payment (or other PPS payment) for any refund that may be required.

Clarifications and liberalizations

- **"Volume or Value of Referrals".** The final rule additionally codifies what it intends to be 'bright-line' tests for CMS to deem that compensation "takes into account the volume or value of referrals" or other business generated and does so in a manner that should assuage stakeholder concerns regarding expansive language in the Fourth Circuit's infamous 2015 opinion in *U.S. ex rel. Drakeford v.Tuomey Healthcare System, Inc*. (792 F.3d 364). In short, compensation between parties takes into account the volume or value of referrals or other business generated only if the formula used to calculate the compensation includes the physician's referrals to the entity or other business generated as a variable, resulting in a change in compensation that correlates with the number or value of the physician's referrals other business generated. However, if the formula focuses on the physician's personally performed work, the fact that corresponding hospital services are billed would not render such a compensation formula improper. Notably, the codified standard is broadly applicable to multiple contexts, including without limitation the indirect compensation arrangements definition, the bona fide employment relationships exception and the personal services arrangements exception.
- **Writing requirements.** The final rule also extended prior CMS guidance liberalizing the writing and signature requirements (as discussed in Health Law Pulse posts here (September 2015) and here (August 2018)), offering parties greater front-end flexibility in satisfying applicable exceptions. Specifically, parties now generally have 90 days to reduce a new arrangement to writing, whereas previously, the parties technically needed to have a writing (or collection of documents) dating to the commencement of arrangement, and the 90-day grace period technically applied only to the *signature* requirement (even if many

practitioners tended to be imprecise in their approach to analyzing such fact patterns). Historically, the Stark Law's strict liability nature made the concept of an aggressive internal audit function a double-edged sword, as such an approach could truncate future liability but might reveal 'foot-faults' that would have to be self-disclosed and settled. Between the 'collection of documents' liberalization, the new application of a 90-day grace period to the *writing* requirement itself (rather than just the *signature* requirement), and the potential ability to combine those liberalizations with the new "limited remuneration to a physician" exception discussed below, parties should generally have a reasonable window to uncover documentation deficiencies and execute a formal agreement consistent with best practices (whether technically required in order to satisfy an exception or not).

- **Payments by a physician.** The final rule also amended the "payments by a physician" exception, which has required (outside of the laboratory context) that the compensation not be specifically covered by another exception, and has been gutted since the "fair market value compensation" exception was expanded in Phase III to cover payments by a physician. Specifically, CMS refined the "payments by a physician" exception's problematic element such that now the compensation must not be specifically covered by a 'statutory' exception (as addressed in the regulations in 42 CFR 411.357(a) – (h)). The amended exception should generally be available to protect arrangements such as where a physician pays a hospital for providing answering services, potentially protecting arrangements that fail to meet the technical requirements of the "fair market value compensation" exception.

Additional new exceptions

In addition to the value-based arrangements exception discussed above, CMS also added new exceptions for "limited remuneration to a physician" and "cybersecurity technology and related services." The "limited remuneration to a physician" exception does not include a 'set in advance' or 'writing/signature' element and is designed to protect modest fair market value remuneration to a physician for the provision of items and services, protecting up to $5,000 (inflation-adjusted) in payments per physician per year that fail to satisfy other exceptions (reflecting an increase from the $3,500 threshold of the proposed rule). Notably, the new exception for "cybersecurity technology and related services" lacks the 15% minimum physician contribution element of the existing "electronic health records items and services" exception, although CMS did modify the latter exception in other helpful ways, including removing the sunset element to make such exception permanent.

Other AKS Safe Harbor changes

The OIG finalized new AKS safe harbors and modified existing safe harbors in the final rule.

- **Patient Engagement and Support.** The Patient Engagement and Support safe harbor protects the provision of in-kind patient engagement tools and supports provided directly by a value-based enterprise (VBE) participant to a patient in a target patient population that are directly connected to the VBE purpose of care management and coordination. The OIG's policy is to be agnostic as to the types of in-kind tools and supports that can be protected by the safe harbor if all the required conditions are met. To fall within the Patient Engagement and Support safe harbor, the tool or support: (i) must be provided directly to a patient by a VBE participant; (ii) must be in-kind and have a direct connection to the coordination and management of the care of the target patient population; (iii) may not include any cash or cash equivalent and does not result in medically unnecessary or inappropriate items or services reimbursed by a federal health care program; (iv) must be recommended by the patient's licensed health care professional; (v) must advance one or more of the following goals: (a) adherence to a treatment regimen determined by the patient's licensed health care professional; (b) adherence to a drug regimen determined by the patient's licensed health care professional; (c) adherence to a follow up care plan established by the patient's licensed health care professional; (d) prevention or management of a disease or condition as directed by the patient's licensed health care professional; or (e) ensure patient safety; (vi) may not be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or an entity specifically excluded from the safe harbor; (vii) must not have an aggregate retail value of $500 on an annual basis; (viii) is not exchanged or used by the VBE participant to market other reimbursable items or services or for patient recruitment purposes; and (ix) is not made available in a manner that takes into account the type of insurance coverage of the patient. Further, for at least six years, the VBE participant must make all materials and records available to the Secretary of HHS, upon request, to establish that the tool or support was distributed in a manner that satisfies these requirements.
- **Cybersecurity Technology and Services.** The Cybersecurity Technology and Services safe harbor is available to all types of individuals and entities and protects certain nonmonetary remuneration in the form of a donation of cybersecurity technology and services. Cybersecurity technology is defined broadly to encompass any software or other type of information technology that is related to the process of protecting information by preventing, detecting, and responding to cyberattacks. To receive protection under this safe harbor, five requirements must be met: (i) the donated technology and services must be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity; (ii) donors may not directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated, nor may they consider future referrals when determining the amount or nature of the technology or services to be donated; (iii) neither a potential recipient nor a potential recipient's affiliated individuals or entities may demand the donation of cybersecurity technology or services as a condition of doing business with the donor; (iv) the donor and recipient must enter into a signed written agreement that provides a general description of the technology or services to be provided over the term of the agreement and outline shared financial responsibility, if any; and (v) the donor is prohibited from shifting the costs of cybersecurity donations to federal health care programs.

- **CMS-Sponsored Models.** The OIG finalized a CMS-Sponsored Models Safe Harbor that permits remuneration between parties participating in CMS-sponsored models, such as distribution of capitated payments and shared savings or losses distributions. The final rule notes that this will provide uniformity and increase predictability for model participants.
- **Electronic Health Records.** The OIG removed the sunset provision in the Electronic Health Records Items and Services safe harbor that required all EHR donations, in order to permanently receive protections under this safe harbor, to have occurred on or before December 31, 2021. The final rule also clarifies that the EHR safe harbor protects certain cybersecurity software and services, adding "including certain cybersecurity software and services" and the term "protect" to the introductory language of this safe harbor. The final rule expands the scope of protected donors to include entities such as parent companies, accountable care organizations (ACOs), and health systems. The final rule deletes the provision that prohibited the donation of EHR items and services that the recipient already possesses.
- **Warranties.** The OIG also modified its existing Warranties safe harbor to "protect warranties that warranty a bundle of items or a bundle of items and services." While this safe harbor will now protect warranties covering services, the OIG explained that it will "not provide protections to warranties that warranty *only* services." To be protected, the OIG also notes that the bundled items and services must be federally reimbursable items and need to be reimbursed by the same Federal healthcare program and in the same Federal healthcare program payment. The OIG finalized a definition of "warranty" directly and not by reference to 15 U.S.C. 2301(6) in an effort to clarify that the warranties safe harbor is available for FDA-regulated drugs and devices.
- **Personal Services and Management Contracts.** The final rule also made changes to the Personal Services and Management Contracts safe harbor. The OIG finalized its proposal to remove the requirement from the personal services and management contracts safe harbor that aggregate compensation be set in advance and to replace it with a requirement that the methodology for determining compensation be set in advance. The OIG also removed the requirement in this safe harbor that agreements that are sporadic, or on a part-time basis, must "specify the schedule, length, and the exact charge for such intervals." The OIG provides the example of a dialysis facility medical director who's schedule is often unpredictable based on the nature of dialysis care and that this requirement to have a predetermined schedule stood in the way of these providers utilizing this flexibility.
- **Outcomes-Based Payments.** The final rule creates a new Outcomes-Based Payments safe harbor to protect payments when the agent that receives the payment "achieve[s] one or more legitimate outcome measure[s]" that are "based on clinical evidence or credible medical support and with specified benchmarks related to quality of care, a reduction in costs, or both." To receive a protected outcomes-based payment, the payment methodology must also be consistent with fair market value, commercially reasonable, and cannot take into account the volume or value of referrals.
- **MSSP ACO Beneficiary Incentives.** The final rule codifies the Medicare Shared Savings Program ACO Beneficiary Incentives safe harbor. The safe harbor aligns with the Balanced Budget Act of 2018 and excludes from the AKS definition of "remuneration" incentive payments for ACOs that operate a "CMS-approved Beneficiary Incentive Program under the Medicare Shared Savings Program."
- **Local Transportation.** The Local Transportation safe harbor is modified to expand the distance limitations to residents of rural areas to 75 miles and removes the mileage limits from inpatient facilities post-discharge. The preamble provides that the safe harbor does not preclude ride-sharing services.

The Congressional Review Act

These final rules were released informally in pre-publication form on the Federal Register website on November 20, 2020. The Congressional Review Act provides that a major rule "shall take effect" 60 days after it is "published in the Federal Register." A "major rule" has an annual effect on the economy of at least $100,000,000. The final rules list the effective date as January 19, 2021. However, the actual publication date in the Federal Register is December 2, 2020, which would mean the final rules would not become effective until after inauguration day. This is an unsettled question of law as to whether the sixty-day clock begins with informal public display or actual publication in the Federal Register. Historically, an incoming administration will issue a memorandum on inauguration day that places a hold on any regulation that has not been finalized.

Stay tuned to the *Health Law Pulse* blog and our webinar series for our insights into these significant final rules and their implications for your organization.

As the world turns: The federal health care agenda in 2021

by Jeff Wurzburg

A new administration is set to arrive in Washington on January 20, 2021, amidst an ongoing global health pandemic, continued uncertainty about the future of the Affordable Care Act (ACA) following the most recent challenge in *California v. Texas*, an uncertain legislative landscape, and with an ambitious administrative agenda.

In reality, the Biden administration's health policy goals are destined to be constrained by the policy focus necessitated by COVID-19. A recent poll from Morning Consult and Politico found that 68 percent of Americans believe controlling the spread of the coronavirus should be a top priority for the Biden Administration.[1] Recognizing this expectation, President-elect Biden quickly appointed a coronavirus task force that is headed by Dr. David Kessler, former commissioner of the U.S. Food and Drug Administration; Dr. Marcella Nunez-Smith of Yale University; and Dr. Vivek Murthy, U.S. Surgeon General from 2014-2017.

The next Secretary of the U.S. Department of Health and Human Services (HHS) will need to immediately extend the Public Health Emergency declaration issued in response to COVID-19. The Public Health Emergency was most recently renewed on October 2, 2020, and is set to expire on Inauguration Day 2021.[2] The declaration has permitted, under Section 1135 of the Social Security Act, extensive waivers of federal regulatory requirements and flexibility for certain stakeholders participating in federal health care programs, including Medicare and Medicaid. As a result, the federal response to the coronavirus has resulted in a rapid expansion in telemedicine utilization; expanded eligibility and benefits; relaxed requirements under HIPAA; modified coverage and payment rules; reduced reporting and audit requirements; and provided flexibility for alternative care sites.[3] In addition, the incoming administration will need to seamlessly continue the coordination and distribution of COVID-19 vaccines. The administration will encounter these challenges on their first day, without consideration of their own policy goals and campaign promises.

Executive Branch priorities

As has become tradition, it is anticipated that on inauguration day a memorandum will be issued by Ron Klain, incoming White House Chief of Staff to President-elect Biden, instructing the heads of all federal agencies to "pause" any regulations that were published in the Federal Register but not yet effective.[4] This provides a new administration the time and space to gain control of the administrative rulemaking process and prevent the release or finalization of certain regulations that do not align with the incoming administration's priorities and prerogatives. However, what the new administration will be able to accomplish through notice-and-comment rulemaking and subregulatory guidance is directly correlated to the bandwidth of the agency. President-elect Biden has made clear his intention for a more robust and reinvigorated response to the COVID-19 pandemic, which will require the dedication of time and resources from all of the operating divisions at HHS.

The Biden administration is expected to strengthen the ACA and undo many of the regulatory and administrative changes to ACA implementation made through rulemaking and subregulatory guidance during the Trump administration. In a back to the future approach, there is likely to be an aggressive approach to rulemaking and subregulatory guidance to quickly signal the overarching change in approach to health policy and a return to many policies from the Obama administration. For instance, it is anticipated the Trump administration's attempts to expand access to short term limited-duration insurance and association health plan will be reversed. Other reversals include eliminating the relaxation of essential health benefit requirements, reinstituting a 90 day open enrollment period, and reinstating Exchange outreach and enrollment funding that were cut by the Trump administration.

Additionally, to expand access to private insurance coverage, the administration likely has authority under section 1311 of the ACA to implement a special enrollment period that would permit individuals and families to enroll in Exchange coverage outside of the annual open enrollment period of November 1, 2020 – December 15, 2020. The Biden administration is likely to quickly withdraw section 1332 waiver guidance, that was of questionable legal authority, and would have permitted states

1 Morning Consult + Politico *National Tracking Poll*, November 24, 2020, available at: https://www.politico.com/f/?id=00000175-f6f9-d692-a975-fefbd92a0000.

2 *Renewal of Determination That A Public Health Emergency Exists*, U.S. Department of Health and Human Services, Oct. 2, 2020, https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.

3 *See generally Coronavirus Waivers & Flexibilities*, Centers for Medicare & Medicaid Services, https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

4 *See e.g. Memorandum from Andrew Card to the Heads and Acting Heads of Executive Departments and Agencies* (Jan. 20, 2001); *Memorandum from Rahm Emanuel to the Heads of Executive Departments and Agencies* (Jan. 20, 2009); *Memorandum from Reince Priebus to the Heads of Executive Departments and Agencies* (Jan. 20, 2017).

to waive some of the most popular ACA consumer protections. It is also expected that the Biden administration will promptly issue rulemaking under section 1557 of the ACA to reverse the controversial 2020 final rule that changed definitions related to discrimination "on the basis of sex," "gender identity," and "sex stereotyping" that were significantly criticized and are currently being challenged in federal court.[5]

The Biden administration will bring about a dramatic change in tone towards the Medicaid program. First and foremost, the Biden administration will encourage holdout states to implement Medicaid expansion. There will be a return to the traditional use of waivers that seek to expand eligibility and types of benefits. In turn, the guidance permitting work and community engagement requirements as a condition of eligibility and block grants is likely to quickly be rescinded.[6] While the Trump administration chose not to finalize the Medicaid Fiscal Accountability Regulation, it is not clear whether or how aggressively a new administration will pursue certain policies that were proposed, some of which were identified as merely codifying existing policy.[7]

Other policy changes implemented by the Trump administration may not be significantly modified. For instance, while the incoming administration will certainly examine the recently finalized changes to the Stark Law and Anti-Kickback Statute, the final rules did not face political resistance and align with prior administrations goals of transitioning to reimbursement based on value. Price transparency and site neutrality policies have found bi-partisan support and are unlikely to see major shifts in policy. Similarly, Medicare Advantage remains popular among beneficiaries and politicians alike.

Legislative priorities

Major health care initiatives, outside of matters related to the coronavirus, are not anticipated to materialize during the 117th Congress. The U.S. House of Representatives will continue to be led by Democrats, albeit with a small majority, and at the time of this *Health Law Check-Up* newsletter, control of the U.S. Senate could turn from two run-off elections in Georgia that will be held on January 5, 2021. Despite the final makeup of the U.S. Senate, there will not exist the type of significant majority needed to enact major reform legislation. Therefore, campaign goals such as coverage expansion through a public option or significantly expanding Medicare eligibility is unlikely.

However, attempts to codify some of the flexibilities undertaken during the public health emergency, such as telehealth expansion, will be pursued. As long as the coronavirus continues to effect public health and the economy, Congress will have to focus on coronavirus response legislation, which could include additional funding and support for providers and other stakeholders. It is also likely that Congress will again attempt to address surprise billing. While efforts in the 116th Congress failed to deliver a federal legislative solution, this issue has remained top of mind to voters as stories of individuals receiving surprise bills related to coronavirus testing and treatment have proliferated.[8]

If Democrats were to gain control of the U.S. Senate on January 5, 2021, the Congressional Review Act could be utilized to overturn regulations finalized in the final months of the Trump administration. Either chamber of Congress may put forth a disapproval resolution on a final rule, and a simple majority is required to pass the resolution. Importantly, should Congress take such an action, in addition to preventing the regulation from taking effect, the agency may not put forward "a new rule that is substantially the same" without authority from Congress.[9]

The future of the Affordable Care Act

The constitutionality of the ACA was once again challenged before the Supreme Court on November 10, 2020 in the case of *California v. Texas*[10]. This time the challenge was brought by the State of Texas and other Republican states that alleged that the ACA became unconstitutional following the passage of the Tax Cuts and Jobs Act, which eliminated the individual mandate penalty for failing to maintain minimum essential coverage.[11] According to the plaintiffs, without the revenue raised by the mandate penalty, it was no longer a tax, and under the Supreme Court's 2012 holding in *NFIB v. Sebelius*[12], is no longer constitutional. In turn, if the mandate is now unconstitutional, they alleged that the entire ACA is unconstitutional because the mandate was so central to the ACA.

In December 2018, Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas agreed, striking down the entire ACA.[13] A year later, in December 2019, the U.S. Court of Appeals for the 5th Circuit agreed with Judge O'Connor's finding that the individual mandate was now unconstitutional.[14] However, they remanded the question about whether the provision may be severed from the remaining parts of the law back to Judge O'Connor. Twenty Democratic states and the U.S. House of Representatives, who had intervened in the case in support of the

5 *Nondiscrimination in Health and Human Education Programs or Activities, Delegation of Authority*, 85 Fed. Reg. 37160 (June 19, 2020).

6 *See SMD 18-002 Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries*, Centers for Medicare & Medicaid Services, Jan. 11, 2018, https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf; *SMD 20-001 Healthy Adult Opportunity*, Centers for Medicare & Medicaid Services, Jan. 30, 2020, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf.

7 *See* Medicaid Fiscal Accountability Regulation, 84 Fed. Reg. 63722 (Nov. 18, 2019).

8 *See* Sarah Kliff, *Coronavirus Tests are Supposed to Be Free. The Surprise Bills Come Anyway.*, The New York Times, Sept. 15, 2020.

9 5 U.S.C. §801(b)(2).

10 Case No. 19-840. Oral argument may be found at: https://www.supremecourt.gov/oral_arguments/audio/2020/19-840; and transcript at: https://www.supremecourt.gov/oral_arguments/argument_transcripts/2020/19-840_1a72.pdf

11 See Pub. L. No. 115-97, § 11081,131 Stat. 2054, 2092 (2017).

12 567 U.S. 904 (June 11, 2012).

13 340 F. Supp. 3d 579 (N.D. Tex. 2018).

14 *Texas v. United States*, 945 F.3d 355 (5th Cir. Dec. 18, 2019).

ACA (which the Trump administration had refused to defend) asked the Supreme Court to review the case. The Supreme Court granted a writ of certiorari and oral arguments were heard on November 10, 2020.

The oral arguments were scheduled for 80 minutes but ended up lasting two hours, with the justices asking a question of each practitioner in order of seniority. It appears likely the ACA will survive this challenge, though likely without the individual mandate. A significant amount of the oral argument was spent addressing whether the plaintiffs have standing and whether, without enforcement of the individual mandate, there is an actual injury they have suffered. The Court also explored the standing through inseverability argument advanced by the plaintiff states. Specifically, the states argued that they are harmed by other provisions in the ACA that are inseverable from the individual mandate. For example, Texas argued that the use of Modified Adjusted Gross Income to determine Medicaid eligibility increased enrollment in the program (despite Texas not expanding Medicaid under the ACA), causing additional expenditures. Many members of the Court appeared skeptical of such an approach to standing, with Chief Justice Roberts noting that it "really expands standing dramatically."

The questions surrounding the constitutionality of the individual mandate were focused on whether the clause is now merely inoperative or precatory, as the states and House of Representatives believe, or alternatively, whether the mandate remains a command to maintain or purchase health insurance coverage as the plaintiffs allege. There was not a clear delineation of where the Justices will land on this question. Referencing the Court's decision in *NFIB*, which found the mandate created a lawful choice to purchase insurance or not, Justice Kagan asked the Texas Solicitor General: "How does it make sense to say that what was not an unconstitutional command before has become an unconstitutional command now, given the far lesser degree of coercive force?" If a majority of the Court agrees with the plaintiffs that the mandate is an unconstitutional command, without the revenue generation that upheld the provision as a tax, then whether the ACA stands or falls will turn on questions of severability.

Oral arguments left the impression that there would be at least five votes that the individual mandate is severable from the remainder of the ACA. Chief Justice Roberts noted that there was "compelling evidence" that the 115th Congress intended the ACA to remain in place after they zeroed out the penalty, but did not repeal the entire law. The Chief Justice, addressing counsel for the House of Representatives, former Solicitor General Donald Verilli, who previously argued in favor the constitutionality of the ACA before the Supreme Court in *NFIB* and *King v. Burwell*[15], said: "I tend to agree with you that it's a very straightforward case for severability under our precedents, meaning that we would excise the mandate and leave the rest of the Act in place, reading our severability precedents." Comments from Justice Kavanaugh also aligned with this approach, noting that the "proper remedy would be to sever the mandate and leave the rest of the act in place." Justice Kavanuagh previously authored the majority opinion in *Barr v. American Association of Political Consultants*, which addressed the Telephone Consumer Protection Act of 1991, addressing the Court's presumption of severability and stating that the Supreme Court "presumes that an unconstitutional provision in a law is severable from the remainder of the law or statute."[16]

There are several potential outcomes: (i) The Court narrowly finds that the plaintiffs lack standing and doesn't address the merits, leaving the entire ACA intact; (ii) The Court finds the mandate to be inoperative or precatory and upholds the mandate, leaving the entire ACA intact; (iii) The Court could find the individual mandate is unconstitutional without a penalty that raises revenue, severing only the individual mandate or the individual mandate and related provisions (the so-called "three-legged stool") such as community rating and guaranteed issue, but leaving the remainder of the law in place; (iv) The Court strikes down the entire law as unconstitutional, creating a health care crisis and instantly burdening the Biden administration and 117th Congress.

No matter the result, the Court's ruling in 2021 will again place the ACA and state of the American health care system at the center of the political universe, likely intensified by the pressures and challenges individuals and stakeholders have experienced during the COVID-19 pandemic. It is worth noting that beyond that, Congress has relied on provisions in the ACA for coronavirus relief efforts and the much of the Trump administration's administrative reforms are reliant on authority under the ACA.

Conclusion

President-elect Biden comes into office constrained by public health and economic challenges that will likely limit his ability to effectuate major changes in health care policy, at least in the short term. The past four administrations have all attempted to reform various parts of the health care system and the Biden administration will be forced to confront the same challenges of rising costs and significant portion of Americans being un- or underinsured. Any changes made through executive or administrative action are likely to face the same types of legal challenges faced by the Obama and Trump administrations. While the overriding challenges stressing the American health system are unlikely to be addressed at the outset of the 117th Congress, stakeholders should expect the robust pace of health care policymaking to continue in the early years of the Biden administration.

15 576 U.S. 373 (June 25, 2015).

16 140 S. Ct. 2335, 2350 (July 6, 2020).

Hospital price transparency and litigation update

by Hayley White

The prices of healthcare items and services has long been an area that the federal and state governments in the United States have attempted to reform. With the cost of healthcare items and services continually on the rise, the government has attempted to create strategies and laws to contain these costs.

Publicizing standard charges for a hospital's items and services as a way to empower consumers and decrease healthcare costs was first introduced by the federal government in 2010 in the Affordable Care Act.[17] Furthermore, Section 2718(e) of the Public Health Service Act (Section 2718(e)) mandated that hospitals make public "a list of the hospital's standard charges for items and services provided by the hospital."[18] CMS initially explained that hospitals could comply with this statute annually by posting their chargemasters, or by posting their policies on how they allow an individual to see this list of charges in response to an inquiry.[19] Then, in its Fiscal Year 2019 Inpatient Prospective Payment System Final Rule, the agency updated its approach to require hospitals to annually post their chargemasters online in a machine-readable format.[20]

However, on June 24, 2019, the federal government's approach to implementing Section 2718(e) and price transparency changed again when President Trump signed an executive order that directed the Secretary of the United States Department of Health and Human Services (HHS) to propose a regulation that would require hospitals to "publicly post standard charge information."[21] The resulting Calendar Year 2020 Hospital Outpatient Prospective Payment System (OPPS) & Ambulatory Surgical Center Price Transparency Requirements for Hospitals to Make Standard Charges Public Final Rule (Final Rule) published by the Centers for Medicare & Medicaid Services (CMS) will require all hospitals in the U.S. to establish, update, and make public a list of the hospital's standard charges for the items and services they provide.[22] Despite ongoing litigation and the coronavirus pandemic, the Final Rule's effective date remains unchanged and there are actions that all hospitals should take to ensure they are in compliance on January 1, 2021.

Requirements under the Final Rule

This Final Rule requires all hospitals to provide public information on their "standard charges" for the items and services that they provide. CMS explains in the Final Rule that it believes that by disclosing hospitals' standard charge information that the "public (including patients, employers, clinicians, and other third parties) will have the information necessary to make more informed decisions about their care."[23]

CMS finalizes "standard changes" to "mean the regular rate established by the hospital for an item or service provided to a specific group of paying patients."[24] Within its definition of standard charges, CMS will require hospitals to publish five types of "standard charges." First, a hospital will have to post its "gross charge" for each item or service, which is the charge that is reflected on a hospital's chargemaster, absent any discounts.[25] Second, a hospital must post its "discounted cash price," which is the charge that applies when an individual pays cash, or cash equivalent, at a hospital for an item or service.[26] Third, a hospital will also be required to publish its "payer-specific negotiated charges," or the "charge that a hospital has negotiated with a third party payer for an item or service."[27] Finally, a hospital will be required to publish de-identified minimum and maximum charges, which are the lowest and highest charges that a hospital has negotiated with all third-party payers for an item or service.[28] The Final Rule defines "items and services" as "all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge."[29] CMS also finalizes "hospital" to mean "an institution in a State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such

17 *See* American Hospital Association v. Azar, 1:19-cv-03619, 2020 WL 3429774, 1-3 (D.D.C. 2020).

18 42 U.S.C. § 300gg-18(e).

19 79 Fed. Reg. 49,854, 50,146 (Aug. 22, 2014).

20 83 Fed. Reg. 41,114, 41,686 (Aug. 17, 2018).

21 Exec. Order No. 13877, *Improving Price and Quality Transparency in American Healthcare to Put Patients First*, 84 Fed. Reg. 30,849 (June 24, 2019).

22 84 Fed. Reg. 65,524 (Nov. 27, 2019).

23 *Id.*

24 84 Fed. Reg. at 65,540.

25 84 Fed. Reg. at 65,541.

26 84 Fed. Reg. at 65,553.

27 84 Fed. Reg. at 65,555.

28 84 Fed. Reg. at 65,554.

29 84 Fed. Reg. at 65,536.

law, or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing."[30]

Each hospital in the U.S. will be required to publish their standard charges in two ways. The first is in a single comprehensive machine-readable file that will make public all of the hospital's standard charges for all hospital items and services.[31] This consumer-friendly file will need to be updated at least annually and must be posted on a publicly available website that can be accessed free of charge.[32] The file should also clearly identify the hospital location with which each standard charge is associated and it must include any code used by the hospital for purposes of billing or accounting for each item of service.[33] The second list that hospitals must make public is one that includes the standard charges for at least 300 "shoppable services," which are services that a healthcare consumer can schedule in advance.[34] In the Final Rule, CMS specified 70 shoppable services that must be included in this list with the other 230 services being chosen by the hospital.[35] The shoppable services list will also need to be easily accessible, without charge, and needs to be searchable by service billing code, description, and payer.[36]

When the Final Rule becomes effective, CMS will have the authority to monitor hospitals' compliance with these requirements by evaluating complaints and auditing websites.[37] If CMS finds a hospital is non-compliant with the Final Rule, the agency may provide a warning notice to the hospital or request an action plan. If the hospital remains non-compliant, CMS may impose a civil monetary penalty of up to $300 per day of non-compliance and will publicize the penalty on the agency's website. Hospitals will have a right to an administrative appeal if they receive a civil monetary penalty.[38]

30 84 Fed Reg. at 65,532.

31 84 Fed Reg. at 65,555.

32 84 Fed Reg. at 65,561.

33 84 Fed Reg. at 65,556.

34 84 Fed Reg. at 65,525.

35 84 Fed Reg. at 65,571-72.

36 84 Fed Reg. at 65,573.

37 84 Fed Reg. at 65,582.

38 84 Fed Reg. at 65,584-89.

American Hospital Association v. Azar litigation

In response to the Final Rule, the American Hospital Association (AHA) and six other healthcare associations and health systems and provider groups filed an action in the United States District Court for the District of Columbia, contending that the Final Rule exceeds CMS's statutory authority under Section 2718(e) and that "standard charges" in that statute can only mean the rates on a hospital's chargemaster.[39] The Plaintiffs also asserted that the Final Rule compelled speech in violation of the First Amendment and challenged CMS's authority under Section 2718(b)(3) of the Public Health Service Act ("Section 2718(b)(3)") to enforce the Final Rule through civil monetary penalties.[40]

However, on June 23, 2020, the U.S. District Court issued a decision in favor of the government. First, the U.S. District Court disagreed with the Plaintiffs that the unambiguous meaning of "standard charges" was solely the rates reflected on a hospital's chargemaster and upheld CMS's definition of standard charges as a reasonable interpretation of Section 2718(e) under the *Chevron* doctrine.[41] The Court explained that if Congress had intended "standard charges" to mean "chargemaster" that they would have simply used this term.[42] Instead, Congress used the term "standard charges" and the Court noted that chargemaster charges are hardly "standard" since 90 percent of hospital patients pay a rate that is not on the charge master. Arguing that there should be meaning to both the term "standard" *and* "charge," the Court further explained that "standard" implies that hospitals have both "non-standard" and "irregular charges," or that there are additional charges for hospital items and services beyond the ones reflected on a hospital's chargemaster.[43] The Court also explained that Section 2718(e) specifically states that a hospital's publicly posted list should include diagnosis-related groups (DRGs) and that it is "undisputed" that the costs associated with DRGs are not included on a hospital's chargemaster.[44] The Court then explained that "this alone" suggests that "standard charges" must mean something beyond what is included on the chargemaster.[45]

The U.S. District Court also found that the Final Rule did not violate the First Amendment because the government is permitted to compel speech when doing so is reasonably related to a public interest. Furthermore, the Court explained that in the case of the Final Rule it advances public interest because it provides healthcare consumers with factual price information to help facilitate informed decisions and it will eventually help to lower healthcare costs.[46] Finally, the Court held that under Section 2718(b)(3) that CMS was empowered to impose civil monetary penalties for failures to comply with the Final Rule's publication requirements.[47]

In response, the Plaintiffs filed a notice of appeal to the U.S. District Court's decision, and on October 15, 2020, the United States Court of Appeals for the District of Columbia heard oral arguments. From the questions asked and tone of the oral arguments, it appears that the judges for the Court of Appeals are unconvinced that the Final Rule is unconstitutional and that hospitals cannot pin down the cost of hospital items and services for a service such as an X-Ray before a patient steps foot in a hospital.[48]

Conclusion

Despite the fact that a new administration could possibly bring in regulatory changes and the pending decision in the Court of Appeals case, hospitals should be in compliance on January 1, 2021. With the final price transparency rule related to healthcare payors being finalized on October 29, 2020, publicly posting charge information appears to be a cost containing strategy that is supported by the federal government and one that is likely to continue in the years to come.[49] Hospitals should, therefore, have a strategy on how they will remain in compliance and annually update their standard charge information moving forward.

39 *American Hospital Association v. Azar*, 1:19-cv-03619, 2020 WL 3429774, 1 (D.D.C. 2020).

40 *Id.*

41 *Id.* at 5-11.

42 *Id.* at 7.

43 *Id.* at 7-8.

44 *Id.* at 9.

45 *Id.*

46 *Id.* at 16-17.

47 *Id.* at 13.

48 *See* Transcript of Oral Argument, *American Hospital Association v. Azar* (No. 20-5193).

49 *See, e.g.,* 85 Fed. Reg. 72,158.

340B Drug Pricing Program update

by Tom Dowdell

The 340B Drug Pricing Program (340B Program) requires drug manufacturers to provide discounts on outpatient drugs in order to have their drugs covered by Medicaid.[50] These discounts are in the form of reduced sales prices for participating "covered entities," which include disproportionate share hospitals, critical access hospitals, sole community hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, and grantee and look-alike federally qualified health centers. The U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) administers the 340B Program. HRSA describes the 340B Program as enabling "covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[51] In the past several years 340B Program drug discounts have been questioned by HHS and the pharmaceutical industry. We discuss herein certain recent developments in the 340B Program.

340B Program drug payment rates

In its calendar year (CY) 2018 hospital outpatient prospective payment system (OPPS) final rule,[52] HHS's Centers for Medicare & Medicaid Services (CMS) reduced Medicare payment for separately payable 340B Program outpatient drugs from average sales price (ASP) plus six percent (ASP+6%) to ASP minus 22.5 percent (ASP-22.5%). This 340B Program new payment policy applies to most hospitals participating in the 340B Program, including disproportionate share hospitals. Rural sole community hospitals, children's hospitals and PPS-excluded cancer hospitals are not subject to the new payment policy.

Several hospital associations and hospitals filed a lawsuit against HHS seeking to block implementation of the 340B Program payment reduction. The U.S. District Court for the District of Columbia and later the U.S. Court of Appeals for the District of Columbia Circuit dismissed the lawsuit on jurisdictional grounds because none of the plaintiffs had presented a claim at the reduced payment rate at the time the complaint was filed.[53] The plaintiffs cured the procedural deficiency by filing claims that had progressed through the appeals process and refiled their lawsuit in the U.S. District Court for the District of Columbia. In a December 2018 decision, the court ruled that HHS, in decreasing 340B Program payment rates from ASP+6% to ASP-22.5%, had exceeded its statutory authority and granted the plaintiffs' motion for a permanent injunction to stop enforcement of the payment reduction.[54] The court also reinstated 340B Program payment to ASP+6% retroactive to January 2018.

In its CY 2019 OPPS final rule, CMS again included the 340B Program ASP-22.5% payment methodology.[55] In May 2019, the U.S. District Court for the District of Columbia again ruled in favor of the plaintiffs, finding that HHS had exceed its statutory authority in reducing 340B Program payment rates.[56] The court, however, did not vacate the rulemaking, which would have required the federal government to reimburse hospitals for the difference in 340B Program payment rates, but rather remanded the matter to HHS to determine equitable relief. In a July 31, 2020, decision, a three-judge panel for the U.S. Court of Appeals for the District of Columbia Circuit in a 2-1 decision upheld CMS's CYs 2018 and 2019 OPPS rulemaking lowering 340B Program reimbursement rates.[57] The court determined that HHS had not exceeded its statutory authority in implementing the rate reduction, but rather the new payment policy was based on a reasonable interpretation of the Medicare statute. On October 16, 2020, the full U.S. Court of Appeals for the District of Columbia Circuit denied the plaintiffs' request to reconsider the three-judge panel's July 31, 2020, decision.

50 42 U.S.C. § 256b.

51 https://www.hrsa.gov/opa/index.html.

52 https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf.

53 *American Hospital Association v. Azar*, No. 18-5004 (D.C. Cir. July 17, 2018) https://www.cadc.uscourts.gov/internet/opinions.nsf/1F81EE00F708DE4C852582CD0052ADDC/$file/18-5004-1740887.pdf.

54 *American Hospital Association v. Azar*, No. 18-2084 (RC) (D.D.C. Dec. 27, 2018).

55 https://www.govinfo.gov/content/pkg/FR-2018-11-21/pdf/2018-24243.pdf.

56 *American Hospital Association v. Azar*, No. 18-2084 (RC) (D.D.C. May 6, 2019) https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-50.

57 *American Hospital Association v. Azar*, No. 19-5048 (D.C. Cir. July 31, 2020) https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf.

In its CY 2021 OPPS proposed rule, CMS proposed to reduce further 340B Program drug payment rates from ASP-22.5% to ASP-28.7%.[58] However, in its CY 2021 OPPS final rule released on December 2, the agency continues the current 340B Program payment policy of paying ASP-22.5% for 340B Program acquired drugs.[59] Rural sole community hospitals, children's hospitals, and PPS-excluded cancer hospitals remain exempted from this payment reduction. These exempted hospitals will continue to report modifier "TB" for 340B Program drugs and will continue to be paid ASP+6%. CMS described that while it is maintaining for now the 340B Program payment policy of ASP-22.5%, the agency will continue to consider and evaluate the appropriateness of using 340B Program hospital survey data to set future payment rates for 340B Program drugs.

Certain pharmaceutical manufacturers impose limitations on access to 340B Program drug pricing and pending administrative dispute resolution process

In the last few months some pharmaceutical manufacturers have imposed limitations on access to 340B Program drug pricing. Certain drug companies have informed hospitals that the companies will no longer provide 340B Program pricing for drugs dispensed through contract pharmacies. Other drug manufacturers have notified hospitals that they now require submission of contract pharmacy claims data. The pharmaceutical companies cite to duplicate discounts related to contract pharmacies as necessitating their actions. The Pharmaceutical Research and Manufacturers of America maintains that HRSA's 2010 policy enabling covered entities to contract with an unlimited number of retail pharmacies to dispense 340B Program drugs has resulted in contract pharmacies making a significant profit on 340B Program drug sales.[60] The American Hospital Association has requested HHS to direct pharmaceutical manufacturers to cease charging hospitals and other covered entities more than the 340B Program price for drugs dispensed by a contract pharmacy.[61]

Congress in the 2010 Patient Protection and Affordable Care Act provided for an administrative dispute resolution (ADR) process for health care providers to take action against pharmaceutical companies for violations of the 340B Program statutory requirements. Under the Obama administration in 2016, HHS issued a proposed rule to establish a binding ADR process. The Trump administration later withdrew the proposed rule. In October 2020, the National Association of Community Health Centers (NACHC) filed a lawsuit in the U.S. District Court for the District of Columbia seeking to compel HHS to implement the ADR process that would enable health centers to take action against the drug companies that have stopped shipping drugs to health centers' contract pharmacies and/or requiring extensive claims data, which actions NACHC claims are a violation of 340B Program statutory requirements. The Office of Management and Budget in a November 17, 2020, posting indicated that a final rule implementing the ADR process is under review.

58 https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf.

59 https://www.cms.gov/files/document/12220-opps-final-rule-cms-1736-fc.pdf.

60 https://www.phrma.org/en/Advocacy/340B.

61 https://www.aha.org/system/files/media/file/2020/08/aha-others-urge-hhs-protect-340b-hospitals-from-drug-companies-trying-undermine-program-letter-8-27-20.pdf.

Telemedicine fraud and abuse enforcement: What to expect next

by Keith M. Rosen and Zach McHenry

Telemedicine has long promised to expand access to health care. While telemedicine has historically been focused on rural and remote areas, the COVID-19 pandemic has redefined the reach of remote health care, and regulators and enforcement authorities have followed suit.

In response to the pandemic, regulators relaxed restrictions on remote health care. For example, in March 2020, the Centers for Medicare & Medicaid Services (CMS) announced that it would temporarily allow all Medicare beneficiaries to receive telehealth services from any location, including their homes.[62] CMS also temporarily expanded the types of health care providers that can offer telemedicine services, and allowed providers to bill for telemedicine services at the same rate as in-person services. The HHS Office for Civil Rights announced that it would exercise enforcement discretion and waive potential penalties for HIPAA violations against providers who use widely available communications technologies (*e.g.*, Skype) in good faith for telehealth treatment or diagnostic purposes.[63]

These regulatory flexibilities were followed by a rise in telemedicine use. According to a HHS report published on July 28, 2020,[64] in February 2020 – the month before President Trump declared the pandemic a national emergency – less than one percent (0.1%) of Medicare primary care visits were provided through telehealth. In April 2020, nearly half (43.5%) of these visits were provided through telehealth. Further, only 14,000 CMS beneficiaries received a telehealth service each week in the pre-pandemic world. A combined 10.1 million beneficiaries received a telehealth service in the period from mid-March through early-July.

These regulatory flexibilities, however, have created opportunities for fraud and abuse, and thus prompted a new priority area for enforcement and compliance. Recent enforcement efforts led by the U.S. Department of Justice (DOJ) allege that telemedicine has facilitated billions in false and fraudulent claims to health care programs. As remote health care continues to scale, this increased scrutiny is poised to grow.

The focus on telemedicine enforcement: Examining recent enforcement actions

The DOJ signaled its growing interest in fraud and abuse facilitated by telemedicine in 2019, prior to CMS temporarily expanding the scope of reimbursable telemedicine services. In April 2019, the DOJ charged 24 individuals, who were associated with five telemedicine companies and 130 medical equipment companies, for their alleged participation in health care fraud schemes that billed Medicare for over $1.2 billion in unnecessary durable medical equipment (DME).[65] In general, the alleged schemes began with call centers, including off-shore call centers, contacting Medicare patients to solicit their personal information. The unsuspecting Medicare patients would then have a remote "consultation" with a medical provider, who then ordered prescriptions for the unnecessary medical equipment. Finally, the medical equipment companies fulfilled the orders, billed Medicare, and sent kickbacks to the original conspirators. In September 2019, the DOJ charged 35 individuals for their alleged participation in a similar telemedicine scheme (this time involving cancer genetic testing laboratories and medically unnecessary cancer genetic tests) that was responsible for over $2.1 billion in losses.[66]

Enforcement scrutiny has expanded during the pandemic. In April 2020, for example, the DOJ charged an owner of two Georgia-based telemedicine companies and others for participating in a scheme that allegedly involved over $60 million in fraudulent claims.[67] The prosecution is part of a series of cases that implicate a range of service providers in the telemedicine ecosystem – physicians, telemedicine companies, patient data brokers, and DME companies – totaling a combined $480 million in fraud. Pleadings in the case highlight how the individuals behind the schemes would identify providers who would write orders for the DME billed to federal health programs, and then pay these providers a fee for each diagnostic consultation.

62 *See* https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak.

63 *See* https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html#:~:text=Today%2C%20the%20Office%20for%20Civil,serve%20patients%20through%20everyday%20communications.

64 *See* https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html.

65 *See* https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

66 *See* https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.

67 *See* https://www.justice.gov/usao-sdga/pr/telemedicine-company-owner-charged-60-million-fraud-scheme.

Most recently, in September 2020, as part of a nationwide operation, the DOJ charged hundreds of defendants for their alleged role in submitting $4.5 billion in false and fraudulent claims to federal health care programs and private insurers related to telemedicine, following a similar pattern.[68] The breadth of these cases covered not only DME orders, but the use of telemedicine to cause the submission of medically unnecessary pharmaceutical, laboratory, and other claims to federal payors.

Returning to the status quo is unlikely: What to expect for future telemedicine enforcement actions

As the expansion of telemedicine enables providers to broaden the scope of patient care, these investigations show that the opportunities for fraud and abuse will follow suit and investigations and enforcement actions will increase. The DOJ and HHS-OIG will continue to increase their scrutiny of the manner in which care is being provided through the expanded telehealth platforms to ensure that the lack of direct patient care does not cultivate an environment in which fraud can occur. The prior investigations, for example, demonstrate that there can be a real risk of payments in violation of the federal Anti-Kickback statute, warranting increased compliance review of new telemedicine offerings.

From a risk/compliance perspective, providers should be cautious of the convenience that telemedicine offers. Enforcement actions will likely target arrangements where providers appear to be offering shorter telemedicine visits with patients in order to maximize billing. Investigators may be similarly drawn to providers with an increased number of new engagements that appear to lack a genuine patient relationship. Regulators are likely analyzing how historical data from in-person patient visits compares to that of remote visits, in order to identify outlier providers. Patient confirmations regarding their visits and resulting treatment may later serve to guard against claims of so-called "phantom visits" and unnecessary services.

Though the virus is far from defeated, providers should begin considering their telemedicine systems and practices in a post-pandemic world. A full return to the status quo is unlikely. Indeed, CMS has already proposed a rule that, if finalized, would permanently add several services to the Medicare telehealth services list.[69] At the same time, many of the temporary regulatory flexibilities were issued, in part, pursuant to the President's March 13, 2020, order designating the coronavirus outbreak a national emergency, and may therefore expire when the designation is lifted. Careful attention to both enforcement actions and regulatory developments will be essential.

68 *See* https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants.

69 *See* https://www.cms.gov/newsroom/press-releases/trump-administration-proposes-expand-telehealth-benefits-permanently-medicare-beneficiaries-beyond.

Outlook on the expansion of reimbursement for telehealth services

by Mark Faccenda

At the start of the COVID-19 public health emergency, the Centers for Medicare and Medicaid Services (CMS) took several steps to expand access to healthcare through telemedicine and remote technologies. In its March 17, 2020, *Medicare Telemedicine Health Care Provider Fact Sheet*, CMS expressed its intent behind expansion of telehealth services. "With the emergence of the virus causing the disease COVID-19, there is an urgency to expand the use of technology to help people who need routine care, and keep vulnerable beneficiaries and beneficiaries with mild symptoms in their homes while maintaining access to the care they need." Over the next several months, CMS expanded the number of services for which Medicare reimbursement is available when provided via telemedicine, as well as having expanded the means by which telemedicine may be delivered. Most importantly, CMS provided reimbursement for telehealth at the same rate as in-person visits while alleviating the requirements that patients reside in rural areas, or be present in certain defined healthcare facilities when receiving care via telemedicine.

The effect of these changes was a dramatic expansion on the number of patients treated and services delivered through telemedicine. CMS Administrator Seema Verma noted in a July 15, 2020, *Health Affairs* blog post that, while 13,000 individuals ordinarily receive telehealth services per week, 1.7 million individuals had received telehealth services in the last week of April 2020 alone, and 9 million beneficiaries had received a telehealth service between March 17, 2020, and June 13, 2020. Notably, the expansion of telehealth services did not, in particular, favor rural beneficiaries over other populations. Ms. Verma had noted that 22% of rural beneficiaries received some form of telehealth service in the above timeframe, whereas 30% of urban beneficiaries received telehealth services during the same time.

Because of this marked expansion of services through telehealth technologies, and the apparent popularity of the receipt of care via telemedicine, CMS has started its evaluation as to whether certain expansions should remain after the COVID-19 public health emergency has ended. In her July 15, 2020, *Health Affairs* blog post, Ms. Verma stated that "CMS is reviewing the temporary changes we made and assessing which of these flexibilities should be made permanent through regulatory action. As part of our review, we are looking at the impact these changes have had on access to care, health outcomes, Medicare spending, and impact on the health care delivery system itself." The factors cited by Ms. Verma demonstrate CMS's joint interest and reluctance in expanding the availability and reimbursement for telehealth services. "Telehealth will never replace the gold-standard, in-person care. However, telehealth serves as an additional access point for patients, providing convenient care from their doctor and health care team and leveraging innovative technologies that could improve health outcomes and reduce overall health care spending."

The three considerations outlined by Ms. Verma, including (i) clinical appropriateness of telehealth services, (ii) appropriate payment rates, given differing resource needs for telehealth services, and (iii) potential for overutilization, fraud and other unwarranted depletions of the Medicare trust, were echoed by the Medicare Payment Advisory Commission (MedPAC) in its September 4, 2020, meeting on expansion of telehealth in Medicare. In investigating whether CMS should make expansion of telehealth reimbursement permanent, MedPAC noted that "telehealth services have the potential to increase use and spending under a [fee-for-service] payment system," and that "current evidence on how telehealth services impact quality of care is limited and mixed." In that September 4, 2020, meeting, MedPAC had proposed a solution under which continued availability of expanded reimbursement might be available for physicians practicing in advanced alternative payment models (A-APMs), but not necessarily for all physicians practicing in the fee-for-service environment. MedPAC surmised that by extending telehealth reimbursement in the A-APM context, Medicare could realize both increased enrollment in shared risk models as well as protection against over-utilization of telehealth services. While CMS has not yet adopted MedPAC's proposed solution to the telehealth expansion question, MedPAC did reiterate its concerns in comments to the 2021 Outpatient Prospective Payment System and Medicare Physician Fee Schedule proposed rules. In its comment to the Medicare Physician Fee Schedule proposed rule, MedPAC recommended that

[P]olicymakers should be cautious in expanding coverage of telehealth services by evaluating whether individual telehealth services balance the principles of cost, access, and quality. For example, expanding the coverage of tele–mental health services at urban originating sites could increase program costs substantially with expanded access to care, but

it is unclear whether the quality of care beneficiaries receive would improve. As CMS considers whether there should be a 30-day limit, 3-day limit, or no limit on the frequency of subsequent telehealth physician visits during a nursing facility stay, CMS should balance the desire to improve access, lower costs, and to provide high-quality care.

Similarly, in its comments to the Outpatient Prospective Payment System proposed rule, MedPAC stated that

[U]se of telehealth services offers a mixed picture. Some studies found that telehealth services can improve access to care, reduce costs, and improve quality. Other studies caution that expanded use of telehealth could harm quality or increase spending. Moreover, it is not clear that the technology will always perform as needed, as malfunctions of the equipment can occur, raising the possibility of increased frequency of adverse events for patients receiving these services.

The Medicare Physician Fee Schedule final rule has just been released. Both Ms. Verma's and MedPAC's comments indicate that telehealth expansion may be not as complete or as immediate as perhaps some in the healthcare industry would prefer. This approach was borne out in the Medicare Physician Fee Schedule final rule, where CMS finalized a handful of procedures for permanent inclusion on the telehealth services reimbursement list, and expanded the list of telehealth procedures that would be eligible through the later of the end of the calendar year in which the COVID-19 public health emergency ends or December 31, 2021, but did not implement wide-scale permanent telehealth services reimbursement policies.

While there have been several legislative proposals focused on expansion of telehealth services, the results of the 2020 elections and pending Senate elections in January make it difficult to predict when such wide-scale telehealth expansion may become a reality. Nonetheless, the potential for expanded reimbursement for telehealth services will likely continue to be a part of the payment policy discussion in the near term.

Little mistakes can lead to big consequences: HIPAA Right of Access Initiative

by Denise Glass

In 2019, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced a new enforcement priority called the "HIPAA Right of Access Initiative." This initiative focuses primarily on three aspects of a patient's right to access to their records: prompt access to their medical records; amounts patients are charged for the medical records and being provided access in a readily producible format of the patient's choice.

By way of background, with certain limited exceptions, the HIPAA Privacy Rules, at 45 CFR 164.524, provide that an individual has a right of access to inspect and obtain a copy of protected health information (PHI) about the individual in a designated record set, for as long as the PHI is maintained in the designated record set. The covered entity is allowed to require that individuals make a request for access in writing, provided that it informs individuals of such a requirement. In most instances, the covered entity must act on a request for access no later than 30 days after receipt of the request, by either accepting the request and providing the requested access or providing a written denial. If the covered entity is unable to act on the request within the 30-day period, the covered entity may have one extension of no more than 30 days, provided that the covered entity provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the records request.

The covered entity must provide the individual with access to the PHI in the form and format requested by the individual, whether in hard copy or an electronic copy, if it is readily producible in such form and format. If it is not, then the covered entity must provide the individual a readable hard copy form or such other hard copy or electronic form and format as agreed to by the covered entity and the individual. The covered entity is permitted to reach out to the individual to discuss the scope, format, and other aspects of the request for access as necessary to facilitate the timely provision of access. A covered entity may provide the individual with a summary of the PHI requested, in lieu of providing access to the PHI itself, but only if the individual agrees in advance to such a summary.

An individual's request for access may direct the covered entity to transmit the copy of PHI directly to another person designated by the individual and, if the signed, written request clearly identifies the designated person, the covered entity must provide the copy to the person designated by the individual.

A covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of (i) labor for copying the PHI requested by the individual, whether in paper or electronic form; (ii) supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; (iii) postage, when the individual has requested the copy, or the summary or explanation, be mailed; and (iv) preparing an explanation or summary of the PHI, but only if agreed to by the individual.

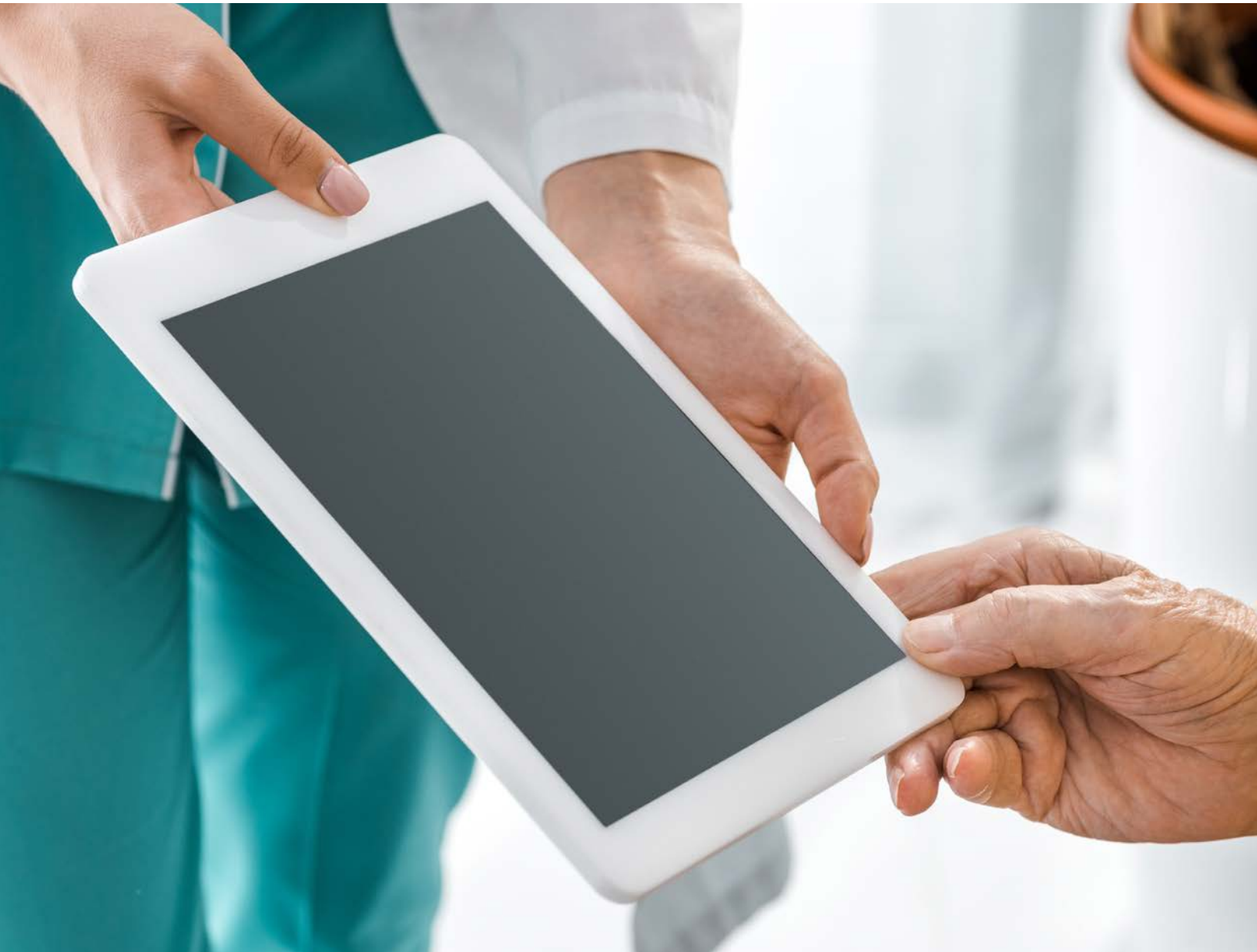
Over the past 14 months, under the HIPAA Right of Access Initiative, OCR has taken twelve enforcement actions, ten of which have been in 2020, with the covered entities ranging from large health systems to a solo practitioner to a nonprofit agency providing services to homeless persons living with HIV/AIDS. Each of these enforcement actions stemmed from a complaint by an individual and resulted in both the assessment of a monetary penalty and a resolution agreement and corrective action plan with OCR. The monetary penalties have been modest in comparison to the penalties assessed for OCR's enforcement actions for unauthorized uses and disclosures of PHI, with the lowest being $3,500 and the highest being $160,000. However, the corrective action plans require that the covered entity take extensive steps to ensure compliance. Each corrective action plan requires, for example, that the covered entity conduct a review of the covered entity's policies and procedures and developing additional policies and procedures as may be necessary. To ensure compliance, the covered entity is further required to provide copies of the policies and procedures to HHS for review and approval. It must also have a plan to implement and distribute the updated policies and procedures, including signed certifications from its workforce members that they have read and will comply with the policies and procedures. As part of the implementation plan, the covered entities must appropriately train workforce members with respect to the updated policies and procedures. The corrective action plans also require that the covered entity assess and revise the policies and procedures annually and report any instances of noncompliance to OCR. Annual reporting to HHS for one to three years, depending on the covered entity, is also required. Finally, the corrective action plans impose certain document retention obligations.

In several of the corrective action plans, OCR delineated the specific areas that the policies and procedures must address. These include delineating the right to and content of notice, timely action by the covered entity, the fees charged by the covered entity, how notice is provided and the time and manner of access, documentation to be maintained by the covered

entity, training protocols for both workforce members and business associates, safeguarding designated record sets, a process to impose sanctions for workforce members who fail to comply with policies and procedures, and maintaining a process for reviewing business associate performance.

When the HIPAA Right of Access Initiative was announced, OCR promised to "vigorously enforce the rights of patients to receive copies of their medical records promptly and without being overcharged." OCR shows no sign of slowing its continued pursuit of enforcement actions under the HIPAA Right of Access Initiative. To that end, it would be prudent for covered entities to review their policies and procedures regarding patient access to records, with particular attention to whether there are processes to ensure that (i) all information requested by the individual is being provided; (ii) such information is being provided in a timely manner; (iii) notice is being provided for any denials of requests for information; and (iv) the fees charged are compliant. Further, if right of access training has not been recently conducted, workforce members should undergo training regarding the handling of and responding to requests for records. Finally, to the extent any portion of handling requests for access is handled by a business associate, covered entities should assess the business associate's performance and take appropriate steps to address any identified deficiencies.

OCR has clearly signaled its intent to hold covered entities accountable to ensure that patients get timely access to their medical records—covered entities would be well-advised to take heed.



Reform of privacy rules related to substance use disorder treatment: Practical implications

by Purvi Maniar and Sarah Jean Kilker

In recent months, there have been several major changes to 42 U.S.C. §290dd–2, often referred to as "Part 2." Part 2 regulations are intended to protect individuals' identifying information and health records obtained by federally assisted treatment programs for substance use disorders ("SUD"). Federally assisted treatment SUD programs are broadly defined and include any SUD programs that receive governmental reimbursement, such as Medicare or that are tax exempt, and thus the applicability of Part 2 is quite broad. The added privacy protocols are a way to encourage individuals to seek and enter treatment without fear of stigma associated with unnecessary disclosure, but were often criticized for hindering coordination of care for patients who suffer from both SUD and other medical conditions. Many healthcare policy experts also questioned whether a separate and more rigid set of rules related to SUD, in fact, reinforced the stigma traditionally associated with SUD as compared to other medical conditions.

The escalation of the opioid crises in recent years, the increased use of technology in treatment and medical record creation, and the increased focus on coordinated care culminated in ongoing pressure from the industry to reform the Part 2 rules. Like many things, the trend towards reform was accelerated during the pandemic and, among other things, the current reforms are intended to increase provider access for patient care coordination and simplify the patient consent process for sharing Part 2 records.

This article examines both the effective and proposed changes to Part 2 and their impact on M&A transactions, enforcement, and telehealth providers.

Explanation of changes

A. 2020 Final Rule

The first set of changes to Part 2 were announced on July 15, 2020, by the Substance Abuse and Mental Health Services Administration ("SAMHSA") (part of HHS) and became effective as of August 14, 2020 (the "Final Rule").[70] Key changes include:

- **Consent requirements**: Although the restriction on the disclosure of SUD treatment records without written patient consent remains intact,[71] the Final Rule allows for patients to consent to disclosure of their records more broadly without naming a specific individual or entity receiving the record. Previously, separate written consent was required for each use of the patient's Part 2 records.
- **Applicability and re-disclosure**: Previously, treatment records created by non-Part 2 providers became subject to Part 2 restrictions if they incorporated any Part 2 SUD records. Now, segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2. This section was modified to facilitate coordination with non-part-2 providers.
- **Permitted disclosures**: In response to confusion regarding what activities fall under "payment and health care operations," a list of expanded examples has been moved from the preamble into the body of the regulation.

B. CARES Act

As the Final Rule was being finalized, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act)[72] further overhauled Part 2. Although the legislative changes to Part 2 are effective immediately, HHS has until March 27, 2021, to finalize the implementing regulations. Key changes include:

- **Consent requirements**: The CARES Act changes go further than the Final Rule and more closely aligns Part 2 with HIPAA regulations. Although written patient consent is still required, once consent has been obtained, the record may be used or disclosed "for purposes of treatment, payment, and health care operations by covered entities (as defined by the HIPAA regulations), business associates, or a Part 2 program as permitted by the HIPAA regulations, which replaces the requirement to obtain patient consent for each use of their Part 2 record.

70 85 Fed. Reg. 42,987 (July 15, 2020)

71 Statutory exceptions to consent still apply in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order.

72 Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No 116-136, 134 Stat 281 (March 27, 2020) (the "Cares Act")

- **Elimination of criminal fines**: The CARES Act legislation adopts HIPAA fines and penalties in place of the Part 2 criminal enforcement mechanism and obligates providers and facilities to comply with HIPAA breach notification requirements.

Impact of Part 2 Changes

(i) Impact on M&A transactions

The Final Rule clarifies provisions related to disclosure of SUD information for treatment, payment and health care operational activities, as there had previously been uncertainty surrounding what activities were covered. Although SAMHSA further clarified that the list is meant to be illustrative and not an exhaustive list of all payment and health care operations activities, the revised list of permitted activities specifically includes "the sale, transfer, merger, consolidation, or dissolution of an organization." The clarification that patient consent is not needed for specific uses, including due diligence (which was not clear prior to this change) gives Part 2 entities (and their counsel) assurance that the use of the Part 2 records throughout the course of due diligence and other activities associated with the sale, merger, or closure of a Part 2 entity will not run afoul of Part 2 regulations. This clarification combined with the CARES Act changes that push Part 2 to align more closely with HIPAA may allow dealmakers to be less burdened by no longer having to comply with two regulatory regimes and feel more comfortable following standard HIPAA procedures concerning due diligence, disclosure of protected health information (PHI), etc.

(ii) Impact on enforcement

The current Part 2 enforcement structure requires a US Attorney to initiate criminal charges and seek fines under the US Criminal Code, which limits fines to $5,000 to $10,000 per violation. The CARES Act legislation establishes civil money penalties for violations of Part 2, replacing the current criminal enforcement mechanism. The legislation adopts HIPAA fines and penalties, which can range from $100 to $50,000 per violation (which can result in massive monetary penalties). Additionally, pursuant to the CARES Act, Part 2 entities are obligated to comply with HIPAA breach notification requirements. If the final regulations promulgated by SAMHSA apply this enforcement authority similarly to how HHS enforces HIPAA, providers will be at greater risk for financial penalties resulting from Part 2 violations. On the other hand, the elimination of a criminal fine should provide relief to Part 2 entities and providers will no longer face the threat of criminal prosecution. Providers should note that Part 2 programs that were not already subject to HIPAA will need to create or review their privacy and security incident plans.

(iii) Impact on providers and telehealth

The Part 2 regulations have been slow to adapt to the increased use of technology for things such as electronic medical record and for treatment via electronic means. The COVID-19 pandemic caused a surge in the need for accessible telebehavioral health services. Both the CARES Act and the Final Rule make it easier for behavioral health providers to coordinate with non-Part 2 providers by streamlining the consent process to allow for broader use of patient records with a single written consent and removing other operational roadblocks.

The CARES Act changes clarify that treatment records created by non-Part 2 providers are not covered by Part 2. Now, Part 2 patient records previously received can be segregated to ensure that new records created by non-Part 2 providers will not become subject to Part 2. This facilitates coordination of care activities among non-Part-2 providers without the fear of inadvertently violating Part 2 by sharing the record with other providers that are part of a SUD patient's non-SUD treatment.

The cumulative changes in consent requirements and re-disclosure rules allow telehealth providers, with patients' written consent, to more easily coordinate care with non-Part 2 providers and conduct efforts such as quality improvement, claims management, and patient safety.

Conclusion

Overall these reformations to Part 2 should streamline the compliance process by more closely aligning the consent and disclosure process with HIPAA rules that are already familiar to healthcare providers and facilities. However, the potential ramifications of non-compliance are now quite significant and the likelihood of enforcement is higher, so care must be taken to ensure compliance policies and trainings are up to date with these new regulations.

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