November 26, 2018

CMS Outpatient Payment, MA Plan Design, and 340B Rules: Cost-Cutting Trends

The Centers for Medicare & Medicaid Services ("**CMS**") recently released major final and proposed rules affecting a range of providers, Medicare Advantage and Medicare Part D plans, and pharmaceutical companies. We summarize the rules here.

Final Medicare Rules on OPPS and ASC Payment Systems, and Expanded Telehealth Opportunities

These final rules, released for prepublication display on November 1 and 2, reinforce a developing trend away from delivery of care in traditional inpatient care settings. Principal changes in the rules reduce reimbursement for services furnished in those hospital off-campus provider-based departments that until now have escaped reduced rates; expand reimbursement opportunities for ASCs and for telehealth services; and reduce medical record documentation requirements.

Proposed Changes for Medicare Advantage and Part D Plans

This proposed rule, released on October 26, would allow Medicare Advantage plans to cover additional telehealth benefits; would improve coordination of benefits for dual-eligible beneficiaries; would update the Part D Quality Star Ratings program; and would strengthen CMS's ability to recover payments that it deems to have been improperly made to Medicare Advantage organizations. While targeted directly at Medicare Advantage plans, the rule would have implications for insurers and providers alike, by opening alternatives to traditional in-office visits for aging populations and implementing oversight requirements with respect to program integrity.

Proposed January Rollout of the 340B Program's Civil Monetary Penalties and Drug Ceiling Price Calculation

This proposed rule, released on November 2, would accelerate implementation of the civil monetary penalty provisions of the 340B Drug Pricing Program, and of the methodology for calculating drug ceiling prices, to January 1. This effectively implements a rule previously finalized in 2017, empowering 340B-covered entities to verify pricing of drugs under the 340B Program, and increasing regulatory scrutiny of drug manufacturers for pricing of covered outpatient drugs.

CMS Releases Final Medicare Rules on OPPS and ASC Payment Systems, and Expanded Telehealth Opportunities

On November 21 and 23, 2018, the Centers for Medicare & Medicaid Services ("**CMS**") finalized rules reinforcing a developing trend away from delivery of care in traditional inpatient care settings. The "**November 23 Final Rule**" is available here, and the "**November 21 Final Rule**" is available here. Among other things, these changes will reduce Medicare reimbursement for services furnished in the remaining hospital off-campus provider-based departments ("**OPDs**") that previously were not subject to a reduced rate; expand reimbursement opportunities for certain outpatient providers and telehealth services; reduce reimbursement for certain non-physician clinicians; and reduce medical record documentation requirements.

Site Neutrality: Reduced Reimbursement for OPDs

Clinic Visits at OPDs

CMS continues to whittle away at the payment differential that has favored furnishing care in a provider-based hospital OPD rather than in a physician office.

OPDs historically have received higher reimbursement than physician offices for delivery of the same services. However, in 2015, the Bipartisan Budget Act ("**BBA**") reduced reimbursement for some OPDs—called non-excepted OPDs (*i.e.*, those established on or after November 21, 2015)—from the higher Hospital Outpatient Prospective Payment System ("**OPPS**") rate to the lower Physician Fee Schedule ("**PFS**") rate. Other OPDs, so-called excepted OPDs (*i.e.*, those in operation or under construction before November 21, 2015, and dedicated emergency departments), did not suffer the rate reduction.

For one particular type of billing code that covers an array of services for new and existing patients—hospital outpatient clinic visit for the assessment and management of a patient, billed under Healthcare Common Procedure Coding System ("**HCPCS**") code G0463—the November 21 Final Rule applies a PFS-equivalent payment rate to all OPDs, including those originally excepted under the BBA. This change is significant because, as CMS's rulemaking preamble stated, the code represents 50% of all separately payable or conditionally packaged services furnished in OPDs annually.

The reduction, which ultimately will reduce OPDs' reimbursement for code G0463 by 60%, will be phased in over time. In 2019, Medicare will reimburse excepted OPDs at 70% of the current OPPS rate for hospital outpatient clinic visits for the assessment and management of a patient. In 2020, it will reimburse OPDs at 40% of the current OPPS rate for the same service. This brings parity to the payment rate for previously excepted and non-excepted OPDs. The aggregate dollar revenue reduction to many hospitals may be significant. CMS's statutory authority to bring regulatory parity to excepted and non-excepted OPDs may be subject to judicial challenge, because the BBA expressly excepted certain OPDs from the payment reduction.

340B Program Site Neutrality Reimbursement

The November 21 Final Rule also adopts a site neutrality policy for drugs and biologicals under the 340B Drug Pricing Program (the "**340B Program**"). Like the site-specific rule above, reimbursements rates historically have varied between excepted OPDs and non-excepted OPDs, whereby non-excepted OPDs are paid a lesser rate. In brief, the new rule applies the same reimbursement rate for drugs and biologicals acquired under the 340B Program whether furnished by excepted OPDs, which are traditionally reimbursed under OPPS, or non-excepted OPDs, which are not. In applying this adjustment, however, CMS may run up against constraints on its authority to determine payments authorized under §

1842(o)(1)(C), the provision governing payments for drugs or biologicals, of the Social Security Act, which may provide fodder to OPDs experiencing reductions to challenge CMS's new 340B reimbursement policy.

CMS Expands Medicare Reimbursement for Ambulatory Surgical Center ("ASC") Procedures

CMS expanded the number of procedures payable by Medicare when furnished in an ASC. CMS did this by expanding the definition for covered services related to "surgery" to include "surgery-like" procedures, and, using that expanded definition as a foundation, added 17 procedures to the ASC Covered Procedures List ("**CPL**"). The principal effect of the change is to expand ASCs' ability to furnish cardiac catheterization services and to further ASCs as alternatives to hospital care.

CMS Intends to Streamline Outpatient Evaluation and Management Visit Payments to Reduce Documentation Burdens on Physicians

The November 23 Final Rule finalized several documentation, coding, and payment changes for office and outpatient Evaluation and Management ("**E/M**") visits. These changes appear to be in response to provider requests to ease medical record requirements. CMS indicated that the changes (i) will obviate the need for providers to re-record relevant patient information, such as history and physical exams, that remains unchanged from the previous visit, and (ii) will eliminate medical necessity documentation requirements when home visits are conducted in lieu of office visits.

Effective in 2021, CMS also compressed E/M visit levels two through four to a single rate for visits other than inpatient visits. CMS, however, did not go as far as it initially proposed. Specifically, CMS originally proposed compressing level five, as well. However, in the November 23 Final Rule, CMS recognized the need to preserve at least level five to reflect variability in care needs for particularly complex patients.

Signaling future changes, CMS indicated that, beginning in 2021, it will grant providers flexibility to use medical decision-making or time to document certain E/M office/outpatient visit levels, and will adopt a new "extended visit" add-on code for use only with certain E/M office/outpatient visit levels when providers need to spend extended time with the patient.

Medicare Adds New Reimbursement Opportunities for Providers via Telehealth

The November 23 Final Rule expands Medicare coverage for telehealth services to reimburse two newly defined physician services: virtual check-ins (HCPCS code G2012) and remote evaluation of video or images submitted by a patient (HCPCS code G2010).

These services, already in use as telehealth capabilities have grown over the years, permit providers to determine whether an office visit or other additional service is warranted for an established patient. Virtual check-ins may include telephone or video conferencing services. Remote evaluations include pre-recorded video or image transmission services, and may also include virtual follow-up within 24 hours via audio or video communication, secure text message, email, or a patient portal. Previously, any routine non-face-to-face communication that occurred prior to or after an in-person visit was part of the in-person visit bundled payment, such as through an E/M visit code. Where these non-face-to-face check-in services did not lead to an office visit, however, the virtual services could not be bundled and were not reimbursed.

The two newly defined reimbursement codes address this gap. If a virtual check-in or a remote evaluation does not result in an in-person office visit, the virtual check-in or remote evaluation will be reimbursed separately. Note, however, that virtual check-ins and remote evaluations that result in an in-person office visit will continue to be bundled into the in-person office visit. Additionally, if a remote evaluation of video or images originates from a related E/M office visit provided within the previous seven days by the same physician, the remote evaluation also will be bundled into the E/M service.

Also significant, CMS did not apply for virtual check-ins or remote evaluations the requirements applicable for other telehealth services that the patient be present at a specified originating site (physician offices, hospitals, community mental health centers, to name a few) and be in a certain geographic area, such as those designated by HHS as a rural health professional shortage area.

While at it, in a similar vein, CMS relaxed originating location requirements for some other telehealth services:

- For remote treatment of a substance use disorder or co-occurring mental health disorder, CMS removed the geographic requirements and added beneficiary residences as permitted originating sites.

- For remote monthly end-stage renal disease ("**ESRD**")-related clinical assessments, CMS removed the geographic requirements and added beneficiary residences and renal dialysis facilities as permitted originating sites.

- For the remote diagnosis, evaluation, and treatment of acute stroke symptoms, CMS removed the geographic requirements and added hospitals, critical access hospitals, and mobile stroke units as originating sites.

While not opening all telehealth services at all locations to Medicare reimbursement, these changes collectively reflect movement in that direction.

Mixed Changes for Non-Physician Services

The November 23 Final Rule will make it easier for group practices and facilities effectively to use and bill radiologist assistants' ("**RAs**") services. In particular, the rule eases physician supervision requirements for RA services by requiring only a direct level of physician supervision, rather than personal supervision, to qualify for Medicare reimbursement.

Currently, RAs are not recognized by CMS as independent health care providers, and cannot directly bill for services such as diagnostic tests. Instead, practices receive Medicare reimbursement for RA services only when those services have personal supervision by a radiologist. Unlike personal supervision, which requires the physician to be present in the room when diagnostic tests are performed by a RA, direct supervision requires only that the physician is "immediately available" to provide assistance and direction throughout the procedure. In implementing these changes, CMS recognized growing radiologist demands across care settings and acknowledged that oversight requirements may not be necessary in light of technological advancements.

In another area, CMS finalized two Medicare reimbursement modifiers for physical therapy assistants ("**PTAs**") and Occupational Therapy Assistants ("**OTAs**") to implement the Bipartisan Budget Act of 2018 provisions that reduce payment for services furnished in significant part by OTAs and PTAs. Specifically, the statute reduces, by 2020, outpatient therapy service reimbursement by 15% when outpatient therapy services are in part or entirely furnished by OTAs or PTAs. CMS has defined "in part" by OTAs or PTAs to mean more than 10% of outpatient therapeutic services. Consequently, providers should carefully document the degree to which OTAs and PTAs are involved in patient care—and the degree to which they perform what CMS considers to be strictly administrative tasks, such as scheduling appointments, greeting, or gowning, which do not count toward the 10% threshold.

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Please contact any member of Ropes & Gray's health care practice group with any questions concerning this Alert.

CMS Proposes Significant Changes for Medicare Advantage and Part D Plans, Including Telehealth Expansion and New Integrity Initiatives

On November 1, 2018, the Centers for Medicare & Medicaid Services ("**CMS**") released a proposed rule (the "**Proposed Rule**"), available here, that updates requirements of the Medicare Advantage program ("**MA**"), also known as Medicare Part C, and the Medicare Prescription drug benefit program ("**Part D**"). The Proposed Rule would:

- Allow MA plans to cover additional telehealth benefits;
- Improve coordination for dual-eligible beneficiaries;
- Update the Part D, as well as certain components of the Part C, Quality Star Ratings program; and
- Take steps toward increasing CMS's ability to recover improper payments made to MA organizations.

While targeted at MA plans, the Proposed Rule would have direct implications for insurers and providers alike by opening alternatives to traditional in-office visits for aging populations and implementing oversight requirements with respect to program integrity.

Additional Telehealth Benefits for Medicare Advantage Plans (including in-home options)

The Proposed Rule would authorize MA plans to offer expanded telehealth benefits as part of the basic benefit package starting in plan year 2020. That would permit MA plans to offer additional telehealth benefits not available through traditional Medicare.

Current Telehealth Benefits

Currently, MA plans are limited in how they may offer telehealth benefits to enrolled beneficiaries. Plans may include only telehealth services covered under Parts A and B in their basic benefit packages. Plans also generally may cover telehealth services only in rural areas and when the patient is present at an institutional health care facility. Current rules do allow MA plans to offer expanded telehealth services as supplemental rather than basic benefits, but supplemental offerings often impose burdensome cost-sharing requirements for beneficiaries.

Expansion of Telehealth Benefits under the Proposed Rule

The Proposed Rule would afford MA plans greater flexibility to offer additional telehealth benefits as part of the MA basic benefits package, rather than as supplemental benefits, thereby reducing co-payment requirements. Under the Proposed Rule, an MA plan could include in its basic benefit package any Part B service that the plan identified as "clinically appropriate" to be furnished through "electronic information and telecommunications technology" including "[s]ecure messaging, store and forward technologies, telephone, videoconferencing, other internet enabled technologies, and other evolving technologies as appropriate for non-face-to-face communication." This change (i) would expand telehealth benefits to all enrollees, regardless of whether they live in a rural or urban area, and (ii) would remove the restriction on the type of facilities at which enrollees may receive telehealth care—rather than requiring MA enrollees to go to a health care facility to receive telehealth services, the Proposed Rule would enable them to receive services from a variety of locations, including their homes.

If finalized, the Proposed Rule would be expected to yield much broader telehealth coverage through MA plans. With more MA plans offering enrollees the convenience of accessing care when and where they want through telehealth, and traditional Medicare lagging in telehealth options, MA plans may become more appealing to beneficiaries than traditional Medicare coverage—and, of course, providers will have more opportunities to provide care through telehealth, and more reason to invest in telehealth technology.

Limitations to the Telehealth Expansion

While greatly expanding telehealth benefits, the Proposed Rule contains several notable limitations.

First, if an MA plan elects to cover a Part B service as an additional telehealth benefit, the plan must also make the service available through an in-person visit. For instance, an MA plan could not include depression screenings as a telehealth benefit unless the plan also covers in-person depression screenings. Similarly, MA plans would be unable to offer a service as a covered additional telehealth benefit if the service is not currently covered by Part B when provided in-person. However, MA plans could continue to elect to offer such service as a supplemental benefit. For example, an MA plan might cover a videoconference to assess dental needs only as a supplemental benefit, since a service primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting teeth is not currently covered by Part B, and therefore could not be offered as an additional telehealth benefit. CMS is currently soliciting comments regarding how to implement this provision.

Second, additional telehealth benefits must be provided through contracted providers that meet plan selection and credentialing standards, although CMS is soliciting comments regarding whether to adjust this requirement.

Third, the Proposed Rule would require any capital and infrastructure costs and investments related to the additional telehealth benefits to be excluded from MA plans' bids, and not reimbursed by CMS.

Market Effect

The Proposed Rule's telehealth provisions have implications across the industry. Most obviously affected are MA plans that, in addition to evaluating what telehealth benefits to offer with the rule's increased flexibility, will need to assess how to stay competitive as an increasing number of plans offer expanded telehealth benefits. The Proposed Rule also would open new avenues of reimbursement and care delivery options for medical centers, hospitals, providers, and even physician practice management organizations. Finally, expanded telehealth reimbursement models would offer investment opportunities in developing telehealth and related-IT markets.

Dual-Eligible Special Needs Plans

D-SNPs coordinate targeted care for high-risk, special needs beneficiaries who are eligible for both Medicare and Medicaid. The Proposed Rule imposes new requirements for greater integration of Medicaid and Medicare benefits in D-SNPs, and unifies Medicare and Medicaid grievance and appeals procedures.

Integration Requirements

The Proposed Rule requires D-SNPs to improve long-term and clinical and financial care integration standards. The Proposed Rule does that by mandating that all D-SNPs fulfill at least one of three criteria for integration of benefits by 2021. Overall, the criteria require providers and health plans to improve coordination of long-term services and supports ("LTSS") or behavioral health services, or to assume greater clinical and financial responsibility for beneficiaries by meeting the requirements of a fully integrated D-SNP or a highly integrated D-SNP. Operationally, integration could take a variety of forms, such as the D-SNP's verifying an enrollee's Medicaid eligibility for LTSS and/or behavioral health services after identifying functional limitations or mental health needs in the enrollee's health risk assessment or individualized care plan.

The Proposed Rule also requires D-SNPs that are not fully or highly integrated to notify their respective Medicaid agency whenever high-risk, full-benefit dual-eligible beneficiaries are admitted to hospitals or skilled nursing facilities, in an attempt to bridge gaps during a beneficiary's transition from a Medicare-covered care setting to one covered under Medicaid. MA organizations offering D-SNPs in 2021 through 2025 that fail to comply with the integration requirements may face an intermediate enrollment sanction.

While the Proposed Rule is intended to reduce administrative burdens and costs for MA plans and their enrollees over time, plans could experience increased costs upon rollout. The heightened care coordination requirements could lead to

increased utilization and coordination with LTSS and behavioral health providers, thereby increasing the burden for MA plans to provide beneficiaries with resources to steer the newly integrated process adequately.

Improving Accountability and Program Integrity

Quality Star Ratings

In addition to its focus on integrating Medicare and Medicaid benefits, the Proposed Rule contemplates changes to the Medicare Star Rating system, which measures the quality of Medicare beneficiaries' experience with health plans. Plans rely heavily on Star Rating to drive profits, both indirectly by attracting customer interest in higher-quality plans and directly by determining plans' eligibility for quality bonus payments and MA rebate percentages.

More specifically, the Proposed Rule updates and adds Star Rating program measures (*e.g.*, controlling high blood pressure, MPF price accuracy, and plan all-cause readmissions) that focus on beneficiary protections and readmissions. While these updates impose heightened obligations on health plans, they may also affect providers, as health plans will likely effect the rule by charging providers with implementing on-the-ground quality changes and imposing financial penalties upon those who fail to make changes.

The Proposed Rule also takes steps to benefit MA plans by (i) accounting for natural disasters and other uncontrollable situations that negatively affect plans' performance, and (ii) modifying the methodology that CMS uses to categorize Star Rating scores, in order to increase the Ratings' stability and predictability over time.

Changes to Medicare Advantage RADV Audit Penalty Calculation and Extrapolation Methodology

Finally, the Proposed Rule seeks to make significant changes to CMS's methodology for calculating penalties for MA claims errors identified in its risk adjustment data validation ("RADV") audits. These changes would eliminate an offset applied to such penalties originally announced by CMS in 2012, which was established as a method to ensure that MA payments be actuarially equivalent to traditional Medicare payments. Eliminating this offset would result in much higher penalty amounts for audited MA organizations. As with other CMS audits, findings will be extrapolated across *all* claims (and not just audited claims) based on the error rate identified in the audit, which heightens the financial exposure that MA plans would face due to errors. Often, participating network provider agreements pass resulting repayment obligations on to physicians and physician practices. Perhaps most significant for audited plans, this methodology would be applied for audits of claims submitted in 2011 or later, so any MA organization that has submitted claims since 2011 would be subject to this new penalty calculation. CMS estimates the proposed changes would result in an estimated $4.5 billion in savings to the Medicare Trust Funds (and thus cost to MA plans) over a ten-year period.

By eliminating the penalty offset, CMS has indicated that it is standing by its position that no adjustments to overpayment calculations in RADV audits are needed, even though the District Court recently ruled to the contrary in *United HealthCare Insurance Co. v. Azar*, No. 16-cv-157 (D.D.C. September 7, 2018). In this case, the court struck down a 2014 Final Rule from CMS that set forth MA audit methodology that did not include an offset to account for diagnosis errors in traditional Medicare claims that were used to calibrate the audit metrics, ruling that the absence of such an offset failed to meet the statutory requirement for actuarial equivalence between MA and traditional Medicare payments. In the Proposed Rule, CMS acknowledges that it is still determining how to respond to this ruling. CMS notes, however, that a study published alongside the Proposed Rule concludes that no offset should be applied to overpayment penalties because diagnosis errors in traditional Medicare claims that are used to calibrate the MA risk adjustment model would not have a statistically significant effect on the identification of overpayments to MA plans in RADV audits. CMS maintains that the District Court did not have the benefit of the study in the administrative record when it announced the *United Healthcare Insurance* ruling. The conflict between these two positions appears to be a potential source for future challenges to CMS's methodology for calculating MA overpayments going forward.

The comment period for the Proposed Rule runs through December 31, 2018. Should you have any questions regarding this Alert, please contact your usual Ropes & Gray advisor.

HHS Proposes January 1, 2019 Rollout of the 340B Drug Pricing Program's Civil Monetary Penalties and Clarified Drug Ceiling Price Calculation

On November 2, 2018, the Health Resources and Services Administration of the United States Department of Health and Human Services ("**HHS**") issued a notice of proposed rulemaking proposing to change the effective date of prior regulations implementing the civil monetary penalty provisions of the 340B Drug Pricing Program (the "**340B Program**") from July 1, 2019 to January 1, 2019. The prior regulations had also clarified the methodology that drug manufacturers should use to calculate ceiling prices for 340B-covered outpatient drugs. If the proposed rule is finalized as written, drug manufacturers that have signed pharmaceutical pricing agreements ("**PPAs**") with HHS may be subject to civil monetary penalties for knowingly and intentionally overcharging 340B-covered entities for covered outpatient drugs beginning next year.

The Public Health Service Act ("**PHSA**") Section 340B was amended in 2010 to authorize civil monetary penalties for overcharges related to 340B drug ceiling prices, and to direct HHS to clarify the 340B drug ceiling price calculation methodology. Although the PHSA had previously established a drug ceiling price calculation, ambiguity remained regarding calculated ceiling prices of less than $0.01 and ceiling prices for newly approved and released drugs. HHS issued guidelines in 1995 indicating that drug manufacturers could estimate 340B ceiling prices for new drugs until sufficient data were available to calculate ceiling prices according to the statute. However, those guidelines did not clarify *how* drug manufacturers should calculate the ceiling price for new drugs, nor did they address ceiling prices of less than $0.01.

The 2010 amendments to the PHSA afforded HHS an opportunity not only to establish civil monetary penalty enforcement standards for overcharging 340B-covered entities, but also to clarify the ambiguities surrounding the 340B drug ceiling price requirement. However, regulations stalled under the Obama administration, which issued a final rule in January 2017 (the 2017 Final Rule). Shortly thereafter, the Trump administration delayed the effective date of the 2017 Final Rule five times, most recently in a final rule issued on June 5, 2018, which delayed the 2017 Final Rule's effective date until July 1, 2019. Although the Trump administration indicated that the delays were required to develop comprehensive policies to address the rising costs of prescription drugs, this approach garnered provider pushback due to the lack of transparency and accountability regarding the ceiling prices that drug manufacturers were actually charging covered entities for drugs under the 340B Program.

On September 11, 2018, the American Hospital Association ("**AHA**") and other 340B provider stakeholders filed a complaint against HHS in the United States District Court for the District of Columbia challenging the repeated delays to the effective date of the 2017 Final Rule. In a press release, the AHA suggested a direct link between its lawsuit and the new proposed rule, which would accelerate the effective date of the 2017 Final Rule from July 1, 2019 to January 1, 2019. Likely not a coincidence, the most recent notice of proposed rulemaking was issued promptly on the heels of that lawsuit, with comments due back to CMS on or before November 23 and rollout scheduled for the beginning of the new year.

The 2017 Final Rule introduces new accountability for drug manufacturers participating in the 340B Program, who could potentially face substantial civil monetary penalties once the 2017 Final Rule goes into effect. The rule will also afford institutional providers an opportunity to monitor future drug prices to confirm compliance with 340B requirements.

Ceiling Price Calculation

The 2017 Final Rule requires that drug manufacturers calculate the ceiling price for covered outpatient drugs on a quarterly basis. Consistent with the PHSA, it defines the ceiling price as the Average Manufacturer Price ("**AMP**") from the preceding calendar quarter for the smallest unit of measure for the drug, minus the Medicaid Unit Rebate Amount ("**URA**") for the drug. Drugs for which the ceiling price is less than $0.01 will have a ceiling price of $0.01.

The 2017 Final Rule also replaces prior HHS guidelines for calculating the ceiling price for newly approved and released drugs by setting forth the methodology that drug manufacturers must use to calculate temporary ceiling prices. The Rule requires manufacturers to estimate the 340B ceiling price for such drugs by subtracting the URA percentage from the wholesale acquisition cost ("**WAC**") of the drug until the AMP is known and no later than the fourth quarter that the drug is available for sale. Once the AMP is known, the manufacturer must charge the 340B ceiling price (AMP minus URA) and, within 120 days, repay the covered entity for any excess amounts charged above that price.

"Knowingly and Intentionally"

The 2017 Final Rule provides that, in most cases, whether an instance of overcharging was knowingly and intentionally carried out (and therefore whether it may lead to the imposition of civil monetary penalties) will be a case-by-case determination based upon the facts. In response to commenter feedback, HHS generally declined to enumerate factors it would consider in conducting such an analysis. However, the 2017 Final Rule does provide that, if a manufacturer does not offer a refund to a covered entity after discovering that it has overcharged the covered entity for a new drug, such an instance of overcharging *would* meet the "knowingly and intentionally" requirement.

Moreover, the 2017 Final Rule enumerates the following situations in which a drug manufacturer would not be considered to have knowingly and intentionally overcharged a covered entity:

- The manufacturer made an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price; and
- The manufacturer sells a new covered outpatient drug during the period the manufacturer is estimating a price, as long as the manufacturer offers refunds of any overcharges within 120 days of discovering the overcharge.

However, the scenarios above would be considered instances of overcharging that would require the drug manufacturer to reimburse the covered entity for any amounts charged above the ceiling price.

The 2017 Final Rule explains that the following situations would not constitute instances of overcharging and therefore would neither require repayment of overcharges nor lead to civil monetary penalties:

- The covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase; and
- The covered entity chooses to order non-340B priced drugs for any reason other than the manufacturer's refusal to sell or make the drugs available at the 340B price.

Conclusion

The proposed acceleration of the effective date of the 2017 Final Rule would increase drug manufacturers' accountability for 340B-compliant prices for covered outpatient drugs beginning January 1, 2019, by requiring prices to be calculated according to the methodology specified in the 2017 Final Rule and introducing civil monetary penalties against manufacturers that knowingly and intentionally overcharge providers. 340B-covered entities would have improved ability to verify that the prices they are paying for drugs under the 340B Program are consistent with PHSA requirements and would be empowered to report manufacturer overcharges to HHS with the knowledge that enforcement action might ensue.