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Surprise, Surprise: Advance Notices in the National Spotlight

Providers continue to struggle with ABNs and other billing notices

By Kyle Gotchy

Hospitals and other providers and suppliers have long struggled to implement consistent policies and procedures to ensure compliance with the range of beneficiary notification requirements imposed by Medicare, commercial payers and state law.

Medicare beneficiary notifications, such as Medicare's advance beneficiary notice of noncoverage (ABN), are intended to advise patients about the potential financial liability they may experience if they elect to receive items or services that may not be covered by their insurance. Failure to comply with such notification requirements may limit a provider's ability to bill a patient for noncovered items or services.

In May, the topic of advance notices gained the national spotlight when several bipartisan groups in Congress introduced new legislation aimed at protecting patients from the financial burden of unexpected, or "surprise," medical bills. Each of the proposed laws includes patient notification requirements, which would further expand the already lengthy list of required notifications.

Given the rising public frustrations with balance billing and the momentum behind lawmakers' current efforts, it appears likely that Congress—in a rare reprieve from partisan gridlock—will likely pass some form of legislation. In anticipation of this looming change, now is the time for providers to review existing requirements and gauge whether the compliance and operational infrastructure exists to meet expanded obligations. This article briefly discusses the proposed legislation, provides a detailed look at several categories of key Medicare notices, and provides an overview of other relevant notice requirements.

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"Surprise" Medical Bill Legislation

So-called "surprise" bills may arise when, for example, patients unwittingly receive emergency care from out-of-network providers, elective services from out-of-network providers (*e.g.*, anesthesiologists, radiologists, pathologists) at in-network facilities, or additional services at out-of-network facilities after receiving emergency

care. To date, Congress has introduced four proposed laws aimed at surprise bills, each of which feature patient notification requirements.

For example, under the Stopping the Outrageous Practice (STOP) of Surprise Medical Bills Act of 2019, a discussion draft of which was introduced by members of the Senate Bipartisan Working Group on May 16, a patient would ordinarily be protected from balance bills if they initially enter a hospital through the emergency department for emergency services and, following stabilization, receive additional nonemergency services from an out-of-network professional or facility. The prohibition on balance billing, however, would not apply if the patient receives written notification that the relevant professional or facility is out-of-network, a cost estimate for the services at issue, and assumes, in writing, full responsibility for the out-of-network costs associated with such out-of-network care. [S. 1531, 116th Cong. (2019).]

Medicare Notice Requirements

Health care provider organizations must comply with a range of beneficiary notification requirements, such as ABNs. Additional Medicare notice requirements include or relate to Medicare financial liability protections and limitations on liability, hospital-issued notices of noncoverage and when an inpatient admission changed to outpatient, among other related notification requirements.

Medicare Financial Liability Protections and Limitations on Liability

The Financial Liability Protections (FLP) provisions of the Social Security Act are intended to protect beneficiaries, providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not cover. [Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 30, § 30.10.] The FLP provisions include the limitation on liability (LOL) provisions under Section 1879(a)-(g) of the Social Security Act, the refund requirements for nonassigned claims for physician services, under Section 1842(l) of the Act, and the refund requirements and the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) refund requirements for assigned and nonassigned claims under Sections 1834(a)(18), 1834(j)(4), and 1879(h) of the Social Security Act.

The LOL provisions, which apply to Part A services and all assigned claims for Part B services, "provide financial relief and protection to beneficiaries, providers, and suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain items and services for which Medicare payment would otherwise be denied." [CMS Manual System Pub. 100-04 Medicare Claims Processing, Transmittal 4197, Jan. 11, 2019, CR 10848.] The Medicare program will not pay for expenses incurred for items or services that are not "reasonable and necessary" or that are for "custodial" care. [42 U.S.C. § 1395(a)(1), (9).] The LOL provisions apply where a determination has been made that payment may not be made because the items or services were "custodial" or were not "reasonable and necessary."

If the beneficiary and the provider of the services "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services" under Part A or Part B, then the LOL provisions provide that the Medicare program will still pay for the items or services. [42 U.S.C. § 1395pp(a).] If, however, the provider "knew, or could be expected to know" that payment could not be made for such services, then the Medicare program will indemnify the beneficiary for any payments he or she made to the provider for the excluded services. [*Id.* at § 1395pp(b).]

Medicare will not make any payments where both the beneficiary and the provider "knew, or could reasonably have been expected to know" that payment could not be made for the items or services.

The amount paid by Medicare to the indemnified beneficiary is considered an overpayment to the provider and is subject to recoupment. In

See Surprise, Surprise…, *page 7*

Are Medicare Beneficiaries Left Out When It Comes to Accessing Innovative Advancements in Medical Care?

Improved Medicare reimbursement tied to innovation and new technology proposed in 2020 IPPS rule

By Juliet M. McBride

Congress took action in 2000 to ensure that Medicare beneficiaries would have access to new, breakthrough technologies that, absent any additional payments, would not be encouraged due to inadequate reimbursement under the existing diagnosis-related group (DRG).

Almost 20 years later, questions remain as to whether Medicare beneficiaries truly have access to the latest innovations in medical care. In the proposed 2020 Inpatient Prospective Payment System Rule, the Centers for Medicare & Medicaid Services (CMS) emphasizes its continued commitment to advancing innovation and new technology to ensure that Medicare beneficiaries can benefit from advancements in medicine and technology without delay.

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Editorial Inquiries:
Mark Polston, Esq.
Phone: 202-626-5540
Email: *mpolston@kslaw.com*

Christopher Kenny, Esq.
Phone: 202-626-9253
Email: *ckenny@kslaw.com*

To subscribe: Call 800/638-8437.

For customer service: Call 800/234-1660.

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This article will briefly cover the background related to additional Medicare payment for new medical services, technologies, and devices and also will address the following key proposals presented by CMS in the proposed rule:

- CMS' proposal to develop an alternative pathway for the inpatient new technology add-on payment for transformative medical devices;
- CMS' request for feedback regarding clarification of the "substantial clinical improvement" criterion required for the additional Medicare payment; and
- CMS' proposal to revise the calculation of the inpatient hospital new technology add-on payment. [*See* 84 Fed. Reg. 19158, 19161-19162 (May 3, 2019).]

Interested stakeholders must submit comments in response to the agency's proposals no later than 5 p.m. EDT on June 24, 2019.

Eligibility Criteria for IPPS Add-On and OPPS Pass-Through Payments

CMS promulgated rules to implement Sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Social Security Act, which authorize the Department of Health and Human Services secretary to establish a mechanism to recognize the costs of new medical services and technologies (collectively referred to as new technologies in this article) under the hospital inpatient prospective payment system (IPPS) for discharges occurring on or after Oct. 1, 2001. [*See* 42 C.F.R. §§ 412.87 and 412.88.]

Annually, CMS announces during its updates to the IPPS in the Federal Register whether a new medical service or technology qualifies for the add-on payment. CMS will only consider applications for the add-on payment if the following criteria are met:

1. The service or technology must demonstrate a substantial clinical improvement over existing services or technologies [42 C.F.R. § 412.87(b)(1).]
2. The service or technology must be new. The technology is considered new if it is not substantially similar to one or more existing technologies and is within two or three years after the point at which data begin to become available reflecting the inpatient hospital code. Once CMS has recalibrated the DRGs based on available data to capture the costs of an otherwise new technology or service, the technology will not be considered new for purposes of the add-on payment. [42 C.F.R. § 412.87(b)(2).]
3. The service or technology must be costly, such that "[t]he DRG prospective payment rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges." [42 C.F.R. § 412.87(b)(2).]
4. The new medical service or technology must receive Food and Drug Administration approval or clearance by July 1 prior to the particular fiscal year considered for the add-on payment.

If the above criteria are met and if costs of the discharge related to the new medical service exceed the full DRG payment (including payments for indirect medical education and disproportionate share hospitals but not outliers), CMS will administer an add-on payment equal to the lesser of (i) 50% of the costs of the new medical service or technology or (ii) 50% of the difference between the full DRG payment and the hospital's estimated cost for the case. [42 C.F.R. § 412.88]. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full Medicare severity DRG (MS-DRG) payment plus 50% of the estimated costs of the new technology or medical service. [84 Fed. Reg. at 19273].

CMS has a similar application and approval process for new medical devices, drugs, and biologicals (collectively referred to as devices in this article) that may be eligible for transitional pass-through payment under the Medicare hospital outpatient prospective payment system (OPPS) as established by Section 1833(t)(6) of the Social Security Act.

CMS will consider an additional pass-through payment if the device has received FDA approval

or clearance (if required), meets newness criterion in that the device is within three years of the FDA's original approval or clearance, and the device will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part, in addition to other criteria. [*See* 42 C.F.R. § 419.66; *see also* CMS Process and Information Required to Apply for Additional Device Categories for Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System (effective March 2016), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.]

If approved, the amount of the pass-through payment for a new device is the hospital's charge for the device, adjusted to the actual cost for the device, less the amount included in the ambulatory payment classification payment amount for the device. [42 C.F.R. § 419.66].

There also is a growing concern that CMS' process lacks clarity or transparency, especially as it relates to how CMS determines whether the innovative treatment or item meets the "substantial improvement" criterion.

CMS' process of approving both the add-on payments for new medical service or technology under the IPPS or the pass-through payments for a new medical device under the OPPS has been met with criticism throughout the years and has been cited as hindering Medicare beneficiaries from receiving the latest advancements in care. There also is a growing concern that CMS' process lacks clarity or transparency, especially as it relates to how CMS determines whether the innovative treatment or item meets the "substantial improvement" criterion.

CMS Proposals

In an effort to demonstrate that its initiatives and payment models are in line with innovations in health care, CMS proposes certain changes to help clarify and streamline the process of approving the add-on payments for new technologies and the pass-through payments for new devices in the proposed rule.

Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices

Acknowledging that there are certain gaps in furnishing the latest technology to the Medicare beneficiaries who could benefit from it, CMS proposes a new route for the add-on payment tied to technology that received approval from the FDA on expedited marketing. Under this proposal, an application process would consider fewer considerations such as cost implications and not all of the typical application criteria noted earlier in this article.

More specifically, in situations when a new medical device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization, CMS proposes an alternate inpatient new technology add-on payment pathway to facilitate access to this technology for Medicare beneficiaries more quickly. [*See* 84 Fed. Reg. at 19162, 19371–19372.]

In particular, CMS proposes that for applications received for IPPS new technology add-on payments for fiscal year 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization (*i.e.*, the device has received premarket approval, 510(k) clearance or the granting of De Novo classification request), such a device would be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS.

Given the criteria applied under the FDA's Breakthrough Devices Program, and because the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, CMS further proposes that the medical device would not need to meet the requirement under 42 CFR § 412.87(b)(1) that it represent in advance that the technology substantially improves, relative to

technologies previously available, the diagnosis or treatment of Medicare beneficiaries. [*See id.*] In connection with this proposal, CMS seeks feedback on whether it should modify the newness time frame set forth in the regulation in order to align more closely to a point when a substantial clinical improvement determination can be made. [84 Fed. Reg. at 19372.]

Request for Comments on Specific Changes or Clarifications to IPPS and OPPS "Substantial Clinical Improvement" Criterion

Repeatedly throughout its preamble to the proposed rule, CMS articulates the goal of establishing, by regulation or subregulatory guidance, "predictability and clarity" that the substantial clinical improvement criterion can be met for the applications for both the IPPS new technology add-on payment and the OPPS transitional pass-through payment for devices. Currently, in evaluating whether a new medical service, technology, or device would represent a substantial clinical improvement, CMS observes whether the technology:

- Offers a treatment option for a patient population unresponsive to currently available treatments,
- Offers the ability to diagnose a medical condition earlier or where it was otherwise undetectable in a patient population, or
- Significantly improves clinical outcomes for a patient population as compared with currently available treatments (*i.e.*, reduced mortality rate, decreased future hospitalizations, decreased pain, reduced recover time, etc.).

CMS is considering adopting six potential regulatory changes (or subregulatory guidance) to the substantial clinical improvement criterion in the fiscal year 2020 IPPS/long-term care hospital PPS final rule for applications received starting in fiscal year 2020 for IPPS (applicable to fiscal year 2021 and subsequent new technology add-on payment) and starting in calendar year 2020 for OPPS.

CMS' proposals are largely developed to help broaden the factors that it will consider in determining whether the new technology or device meets the substantial clinical improvement requirement. The agency outlines the following six proposals that it seeks feedback on:

- Whether the new technology would be broadly adopted among applicable providers and patients, tilting more towards a patient-centered approach in assessing whether the new technology represents a substantial clinical improvement. [84 Fed. Reg. at 19369.]
- Adopting a definition that the term "'substantially improves' means, *inter alia*, that the new technology has demonstrated positive clinical outcomes that are different from existing technologies," with the goal of providing more clarity on how the agency will evaluate whether an improvement has occurred. [84 Fed. Reg. at 19370.]
- Establishing a policy that acknowledges that "substantially improves" can be met through "real-world data and evidence," such that measurable improvements are not confined to clinical settings and can extend to data gathered in scenarios outside of a clinical trial or clinician's office. [*Id.*]
- Proposing to consider various types of relevant information that could help to determine whether the new technology meets the substantial clinical improvement standard and making clear that a peer-reviewed journal article is not required in order to meet the requirement. [*Id.*] Relevant information could include a white paper, inferences from other literature or evidence, case studies, and other materials, whether published or not. [*Id.*]
- Recommending that an applicant can meet the substantial clinical improvement criterion for any subset of beneficiaries regardless of the size of that subset of patient population. [*Id.*]
- Proposing that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology, consistent with CMS' current policy. [84 Fed. Reg. at 19371.]

In addition to a request for feedback on the above six proposals, CMS also seeks comments

more broadly on the type of additional detail and guidance that the public and applicants would find useful as it relates to the substantial clinical improvement criterion for potential rulemaking in future years, including, for example, whether CMS should consider evidence regarding the off-label use of a new technology. [84 Fed. Reg. at 19162, 19369.]

Proposed Revision of the Calculation of the Hospital New Technology Add-On Payment under the IPPS

After consideration of the concerns raised throughout the years by commenters that the 50% limit to the new technology add-on payment does not allow for accurate payment of a new technology with unprecedented high costs, CMS proposes to increase the maximum add-on amount for the inpatient new technology to 65%, acknowledging that capping the add-on payment amount at 50% could, in certain situations, fail to provide a sufficient incentive for the use of the new technology. [84 Fed. Reg. at 19162, 19373.]

Therefore, CMS proposes that, starting with discharges on or after Oct. 1, 2019, if the costs of a discharge involving a new technology exceed the full DRG payment (including payments for indirect medical education and disproportionate share hospitals but not outliers):

> Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment would be limited to the full MS–DRG payment plus 65 percent of the estimated costs of the new technology or medical service. [84 Fed. Reg. at 19373.]

In Summary

In closing, as hospitals, health systems, and device suppliers collaborate more frequently with individuals and entities on the frontline of health care innovation, they should take interest in the proposals presented by CMS in the proposed rule and consider ways of becoming involved in providing feedback to CMS.

It is critical for the community delivering the health care services and devices to Medicare beneficiaries to become engaged in the process, if not already, by submitting comments in response to the proposed rule and by becoming active participants in the various CMS town hall meetings and periodic requests for feedback as it relates to the reimbursement of innovative services, technology, and devices. ■

About the Author

Juliet M. McBride is a partner in King & Spalding's health care industry practice group in Houston. She may be reached at *jmcbride@kslaw.com* or 713-276-7448.

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contrast, Medicare will not make any payments where both the beneficiary and the provider "knew, or could reasonably have been expected to know" that payment could not be made for the items or services. [*Id.* at § 1395pp(c).] In such cases, the limitations on the beneficiary's liability will not apply, and providers may look directly to the beneficiary for payment.

Providers will generally be presumed to have known that items or services were excluded from coverage as custodial or as not reasonable and necessary. As evidence of a provider's knowledge, contractors will look to whether the contractor received prior notice from a quality improvement organization (QIO), intermediary or carrier that the items or services—or reasonably comparable items or services—were not covered. Providers will also be considered to have constructive knowledge based on their receipt of Centers for Medicare & Medicaid Services (CMS) notices, publications in the Federal Register, national coverage determinations, and the provider's knowledge of what are considered acceptable standards of practice in the local medical community. [42 C.F.R. § 411.406; Medicare Claims Processing Manual, § 30.2.1.]

Advance Beneficiary Notice of Noncoverage

Where the Medicare program has made a coverage decision that items or services are not reasonable and necessary under Section 1862(1)(1)(A) of the Social Security Act, a provider may still determine that a patient may benefit from a particular item or service. Where a provider believes an item or service may benefit a fee-for-service beneficiary but expects a denial from Medicare, the provider can avoid financial liability for those items or services by notifying the beneficiary in writing, using a standardized ABN, Form CMS-R-131, about the potential denial and the attendant financial consequences.

The ABN is not used for items or services provided under Medicare Part C or D. [Medicare Claims Processing Manual, § 50.3.] The form and instructions for its implementation can downloaded at: *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html.*

If a beneficiary elects to receive the items or services described in the written notification and Medicare does deny the provider's claims for those items or services, the beneficiary will not be afforded to protection under the LOL provisions and will instead be held personally liable for paying the provider's bill. [42 C.F.R. § 411.404; Medicare Claims Processing Manual, §§ 30.40, 50.2.1.] Such charges are not limited to the Medicare fee schedule and may be the provider's usual and customary fee. [Medicare Claims Processing Manual, § 50.7.3.]

There are three points during the course of a patient's treatment that may trigger a provider's obligation to issue an ABN. [Medicare Claims Processing Manual, § 50.5.] Referred to by Medicare as "triggering events," they include:

- *Initiations*, which occur at the beginning of a new patient encounter, treatment or a plan of care.

- *Reductions*, which occur when there is a decrease in a component of care (*e.g.*, frequency, duration). Providers do not need to issue an ABN every time a reduction occurs. Instead, ABNs are only required where a reduction occurs and the beneficiary desires care that is no longer considered reasonable and necessary for Medicare purposes.

- *Terminations*, which occur when there is a discontinuation of items or services. The provider must issue an ABN if the beneficiary wants to continue receiving care that is subject to termination because it no longer reasonable and necessary.

Providers using the ABN must be careful to comply with CMS' implementation requirements. Where a notifier provides defective notice, it may be challenging for the notifier to claim it did not know that the claims for the subject items or services would be denied. CMS has instructed contractors that "the issuance of the notice (albeit defective) is clear evidence of knowledge." [Medicare Claims Processing Manual, § 50.2.2.]

Where a notifier provides defective notice, it may be challenging for the notifier to claim it did not know that the claims for the subject items or services would be denied.

While there is some room to customize the ABN, given the consequences of defective notice, providers should be wary of using the form to express their creative inclinations. [Medicare Claims Processing Manual, § 50.6.1.G.] Information that the notifier must communicate through the ABN includes the item or service that Medicare may not cover, a brief explanation why such items or services may not be covered (*e.g.*, Medicare does not pay for this test for your condition), and a reasonable estimated cost for all items or services listed in the ABN. [*See* ABN Form Instructions, available at: *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/ABN-Form-Instructions.pdf.*] The ABN must also provide the beneficiary with the choice between: (a) receiving the item/service and requiring the notifier to bill Medicare, which will result in a payment decision that can be appealed; (b) receiving the item/service and paying out of pocket without the provider submitting a claim to Medicare; and (c) refusing the item/service.

To be effective, the ABN must be delivered to the patient (or an authorized representative) far enough in advance of delivering the potentially noncovered items or services to allow sufficient time for the patient to consider all available options and make a rational, informed decision without undue pressure. [Medicare Claims Processing Manual, §§ 40.2.1, 50.7.1.] ABNs, however, must not be given to patients during an emergency, including in situations where the Emergency Medical Treatment and Active Labor Act (EMTALA) applies, or under other conditions where the patient is in great duress. [Medicare Claims Processing Manual, §§ 40.2, 40.4.]

The ABN must be delivered far enough in advance to allow sufficient time for the patient to consider all available options.

The notifier must retain the original signed and dated ABN and provide a copy to the beneficiary. The general retention period for the ABN is five years from discharge/completion of the delivery of care, as long as there are no other applicable requirements under state law. If a beneficiary is not given a copy and later alleges the written notice presented by the Medicare contractor is materially different than the version the beneficiary signed, the contractor "will give credence to the beneficiary's allegations," possibly undermining the notice's effect. [Medicare Claims Processing Manual, § 40.2.1.]

Providers may elect to issue ABNs electronically but must provide the beneficiary with the option to receive a paper version. Even when ABNs are issued electronically, the beneficiary must still be given a paper copy for his/her own records, meaning providers that email copies of electronically signed ABNs to beneficiaries will not meet the documentation requirements. [Medicare Claims Processing Manual, § 50.7.1.D.]

CMS has identified certain practices that will vitiate an ABN's effectiveness and will not protect the notifier from financial liability for the items or services:

- *Routine notices*: Providers should not provide written notice where there is no specific, identifiable reason to believe Medicare will not pay for an item or service. This includes providing "blanket notices" for all claims or services.

- *Generic notices*: Notices will not be effective if they "do no more than state that Medicare denial of payment is possible, or that the notifier never knows whether Medicare will deny payment." Notices must instead communicate "a genuine reason" that denial "is expected."

- *Signed blank notices*: A notifier may not have a beneficiary sign a blank ABN and subsequently populate the form with the required information. [Medicare Claims Processing Manual, §40.2.2.C.]

The agency has also identified several circumstances when routine written notices will be considered effective, including the following:

- *Items and services that are always denied due to lack of medical necessity*: ABNs may be issued where a national coverage decision (NCD) provides that a particular item or service is never covered, under any circumstance, as not reasonable and necessary under Sec. 1862(a)(1) of the Social Security Act.

- *Experimental items and services*: Routine ABNs may be issued in this circumstance because experimental items and services are denied as not reasonable and necessary because they are not proven to be safe and effective.

- *Frequency-limited items and services*: When Medicare has established a frequency limit through statute, regulation, NCD or a contractor's local coverage determination (LCD), a provider may issue routine ABNs as long as the frequency limit is identified as the reason for the expected denial. [Medicare Claims Processing Manual, §40.2.2.C.]

ABNs are not required for care that is statutorily excluded from coverage under Medicare or most care that fails to meet a technical benefit requirement (*i.e.*, lacks required certification). [Medicare Claims Processing Manual, § 50.3.2.]

Hospital-Issued Notices of Noncoverage

Hospitals provide hospital-issued notices of noncoverage (HINNs) to beneficiaries prior to admission, at admission or at any point during an inpatient stay if the hospital determines that the items or services the beneficiary is receiving, or is about to receive, are not covered because they are not reasonable or necessary, not delivered in the most appropriate setting or custodial in nature. The model HINNs and the instructions for their use can be accessed at: *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/HINNs.html.*

CMS cannot prohibit changes to the model HINNs, but any change to the model could lead to a finding that the notice was ineffective.

CMS produces the HINNs in model language, as the notices have not been subject to clearance under the Paperwork Reduction Act of 1980, 44 U.S.C. §§ 3501-3521. This means CMS cannot prohibit changes to the model HINNs, but any change to the model could lead to a finding that the notice was ineffective. That said, CMS has instructed intermediaries only to make a finding that a notice was invalid if a notice lacked certain mandatory elements. [*See* HINN 11 Instructions.]

The four types of HINNs are described below:

- *Preadmission/admission (HINN 1)*: A hospital issues the HINN 1 when the hospital (acting directly or through its utilization review (UR) committee) has determined prior to—or at the time of—admission that the beneficiary is facing a noncovered hospital stay because the services may not be considered reasonable and necessary in the beneficiary's particular case, could be safely provided in another setting or the care may be considered custodial in nature. The notice advises the beneficiary of his or her right to request an expedited review of the admission's medical necessity by a QIO.

  If the QIO disagrees with the hospital's determination, the beneficiary must be refunded any amount collected except applicable coinsurance and deductibles and convenience items not covered by Medicare. In comparison, if the QIO agrees that the stay is not reasonable and necessary, the beneficiary will be personally responsible for all services as of the date specified by the QIO.

- *Hospital-requested review (HINN 10)*: If a hospital (acting directly or through its UR committee) determines that a beneficiary no longer requires inpatient care but is unable to obtain the agreement of the physician, the hospital may request an expedited determination by the QIO. If the hospital seeks a QIO's review, then the hospital must notify the beneficiary that the hospital has requested a review based on the HINN 10 model language.

  The QIO is required to make its determination and notify the beneficiary, hospital and physician within two working days of the hospital's request and the QIO's receipt of any pertinent information submitted by the hospital. [42 C.F.R. § 405.1208; Medicare Claims Processing Manual, §§ 220, 220.1, 220.2, 220.4.]

- *Noncovered service(s) during covered stay (HINN 11)*: Hospitals may charge inpatients for noncovered diagnostic and therapeutic services provided during a covered stay that are excluded from Medicare coverage as medically unnecessary. Such services must not be bundled into or integral to payment or treatment for the diagnoses justifying the covered inpatient stay.

  For the hospital to charge the beneficiary for the noncovered services, the hospital must provide the beneficiary with written notice based on HINN 11 that identifies the published Medicare coverage policy (NCD or LCD) that confirms the item is not covered due to a lack of medical necessity. The notice also informs the beneficiary that the Medicare intermediary will make the payment decision when it processes the hospital's claim and that the beneficiary may also seek a QIO review. [42 C.F.R. § 412.42(d); HINN 11 Instructions.]

- *Noncovered continued stay (HINN 12)*: A hospital must notify a patient when the hospital believes Medicare will not cover the patient's continued inpatient stay. The HINN 12 is issued in connection with the hospital discharge appeal notices (i.e., the Important Message from Medicare and the Integrated Denial Notice).

Related Medicare Notification Requirements

Exhibit 1 summarizes the different advance notices that hospitals may need to provide to beneficiaries of Medicare fee-for-service and Medicare Advantage (MA) plans in different contexts. A fuller version of the table, which includes notice requirements that apply to other types of providers and suppliers, can be accessed on CMS's Beneficiary Notices Initiative website: *https://www.cms.gov/medicare/medicare-general-information/bni/index.html.*

Code 44 Billing: Inpatient Admission Changed to Outpatient

When a hospital UR committee determines that an inpatient admission does not meet the hospital's inpatient criteria, the hospital may change the beneficiary's status from inpatient to outpatient and submit an outpatient claim for

Exhibit 1: Related Medicare Notification Requirements

Type of Notice	Medicare Program	Type of Notice	Purpose
Advance beneficiary notice of noncoverage (ABN) (Form CMS-R-131)	Fee for service (FFS)	Financial liability notice	Issued to transfer financial liability to beneficiaries to convey that Medicare is not likely to provide coverage in a specific case.
Hospital-issued noticed of non-coverage (HINN)	FFS *HINN 10 may be used for Medicare Advantage (MA)	Financial liability notices	Issued to transfer financial liability to beneficiaries if the hospital determines that the care the beneficiary is receiving, or is about to receive, is not covered in a specific case. There are currently four different HINNs: HINN 1, 10, 11 and 12.
Important Message from Medicare (IM, Form CMS-R-193)	FFS and MA	Hospital discharge appeal notices	Given only if a beneficiary requests expedited review of a discharge decision. Explains the specific reasons for the discharge.
Detailed Notice of Discharge (DND, Form CMS-10066)	FFS and MA	Hospital discharge appeal notices	Given only if a beneficiary requests expedited review of a discharge decision. Explains the specific reasons for the discharge.
Integrated Denial Notice (IDN, Form CMS-10003)	MA	Denial notices	Issued upon denial, in whole or in part, of an enrollee's request for coverage and upon discontinuation or reduction of a previously authorized course of treatment.
Medicare Outpatient Observation Notice (MOON, Form CMS-10611)	FFS and MA	Hospital notice of observation services and are not inpatients	Issued to inform Medicare beneficiaries (including health plan enrollees) that they are outpatients receiving observation services and are not inpatients of a hospital or critical access hospital (CAH)

medically necessary Part B services that were furnished to the beneficiary, provided certain conditions are met. In such cases, the UR committee must give written notification, no later than two days after its determination, to the hospital, the patient and the responsible practitioner. The hospital must report Condition Code 44 when billing Part B for these services. [*See* MLN Matters SEO622 (Sept. 10, 2004).]

Notices Required by Commercial Payers

Like Medicare, most commercial payers impose their own notification requirements, often referred to as either advance notices of noncoverage (ANN). Providers typically must provide the ANN to plan members under circumstances akin to those that apply to Medicare ABNs—when the provider believes the item or service is not covered or not medically necessary.

Providers must be familiar with each commercial payer's particular requirements.

Commercial payers may mandate the use of template notices, provide suggested formats or simply require providers to include certain information in their communications with plan members. Although the terms and requirements used in the commercial context parallel those used by the Medicare program, in order to avoid incurring unnecessary financial liability, providers must be familiar with each commercial payer's particular requirements.

In Summary

As Congress prepares to address the public outcry over surprise medical bills, providers should anticipate the creation of new notice requirements. Providers who have already implemented comprehensive and consistent processes for complying with their existing obligations should have little difficulty adapting to the new obligations.

Unfortunately, anecdotal experience indicates many providers already struggle to comply with the status quo. Rather than waiting for the list of required notifications to expand, providers should undertake proactive measures to review their notification practices and prepare the stakeholders charged with overseeing the day-to-day implementation of the same. ■

About the Author

Kyle Gotchy is a senior associate in King & Spalding's health care practice group in Sacramento, California. He may be reached at *kgotchy@kslaw.com.*