



## Keeping Up with the New Medicare Rules

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The Centers for Medicare and Medicaid Services (CMS) has published a flurry of new proposed and final rules this summer regarding payment rates and policies affecting Medicare providers, Medicare Advantage (MA) and Part D plan sponsors, and beneficiaries. The following offers a summary of some of the most noteworthy changes, most of which seek to provide greater flexibility to plan sponsors to offer Medicare patients greater choice in benefits and to reduce beneficiary costs.

### Final Rules and Guidance Documents

#### *Loosening the Uniformity Rules in Medicare Advantage*

In April of this year, CMS finalized a rule that will provide [Medicare Advantage](#) plans greater authority to tailor their supplemental benefits to the unique needs of their patients.<sup>1</sup> Current law requires that MA plans provide uniform benefits at a uniform premium to all enrollees in a specific plan, which had previously been interpreted to include uniform cost-sharing. CMS is now interpreting the law in a way that allows MA plans, for enrollees that meet specific medical criteria, to reduce cost-sharing for certain benefits, to offer certain supplemental benefits, and to provide lower deductibles—as long as all similarly situated enrollees are treated the same and that such tailored benefits are for services medically related to the shared medical condition. For example, loosening the program's uniformity requirements will allow plans to offer diabetic patients reduced cost-sharing for endocrinologist visits or more frequent foot exams. CMS reiterates that this rule change does not in any way change the program's non-discrimination rules, and MA plans may not restrict access to or condition the coverage of a good or service based on health-status related factors.

This rule change supplements new authorities that the recently passed Bipartisan Budget Act of 2018 (BBA) provided. The BBA included the CHRONIC Care Act and expanded the current value-based insurance design demonstration (VBID) that the CMS Innovation Center is conducting. The CHRONIC Care Act authorizes CMS to waive the uniformity requirement beginning in 2020 specifically for supplemental benefits offered to chronically ill patients. These benefits will not be required to be medical benefits, and may include services such as meal



delivery, installation of handrails or wheelchair ramps at a patient's home, or providing transportation to doctors' appointments via ride-hailing companies. The BBA will expand the MA VBID demonstration to all 50 states in 2020. VBID plans are designed to promote the use of health care services with the highest value—the best outcomes at the lowest cost—by, for example, reducing patient cost-sharing for those services.<sup>2</sup>

### *Eliminating “Meaningful Difference” Requirements in MA and Part D*

Today, each MA and [Part D](#) prescription drug plan that a plan sponsor offers in a given county is required to be meaningfully different from the sponsor's other plans. The “meaningful difference” standard applies to out-of-pocket (OOP) costs and formulary structures.<sup>3</sup> This provision seeks to balance the desire to have numerous plan options available while limiting the confusion that may arise from having too many options. This requirement, however, also limits the ability of plan sponsors to offer innovative benefit designs tailored to different groups of beneficiaries with different needs.

In the final MA and Part D rule for 2019, CMS has eliminated this requirement for MA plans<sup>4</sup> and Part D Enhanced Alternative (EA) benefit design plans (relative to other EA plans offered by the same plan sponsor).<sup>5</sup> The elimination of this requirement should allow for more plan options with subtle yet significant differences. Such differences for MA plans may include different provider networks, premiums, inclusion or exclusion of Part B premium buy-down, and different estimated out-of-pocket costs. Part D EA plans will still be required to be meaningfully different from basic Part D plans, but plan sponsors will no longer have to show that a meaningful difference exists between each of their own EA plans. Differences for Part D EA plans may now include OOP cost designs with similar actuarial values but differences in how and when beneficiaries must pay; for example, one plan may have a high deductible but low coinsurance rates whereas another has higher coinsurance rates but no deductible.

### *Reducing Part D Beneficiaries' Out-of-Pocket Costs*

Also included in the final MA and Part D rule for 2019 were several provisions to reduce beneficiaries' OOP drug costs.<sup>6</sup> Part D plans will now be able to substitute a generic drug in place of a brand-name drug as soon as it becomes available, which typically reduces significantly beneficiaries' cost-sharing liability. For purposes of the Low-Income Subsidy (LIS) program, where LIS beneficiaries' OOP



costs are fixed dollar amounts depending on whether a drug is a brand-name or generic, biosimilar products will now be treated as generic drugs, which will also reduce LIS beneficiaries' cost-sharing as well as the federal government's costs. CMS also modified rules regarding the tiering exceptions process in place for beneficiaries who are unable to take a lower-cost alternative drug due to safety or efficacy concerns. The exceptions process allows beneficiaries to request an exception from the cost-sharing amount they are supposed to pay for the drug they are taking and instead pay the lesser cost-sharing amount for the lower-cost drug on a lower tier on the formulary. Part D plans will no longer be allowed to exclude dedicated generic tiers from the tiering exceptions process, and beneficiaries granted an exception must be given the cost-sharing amount for the lowest tier on which an alternative drug is available.

### *Recognizing Medicare Advantage Plans as Advanced APMs*

In 2015, Congress passed the Medicare and CHIP Reauthorization Act (MACRA), which established a new payment system for Medicare providers. This new payment system requires providers either 1) participate in [Advanced Alternative Payment Models](#) (AAPMs) and be eligible for a bonus payment, or 2) report quality and payment data under the [Merit-based Incentive Payment System](#) (MIPS) and be subject to financial bonuses or penalties depending on their outcomes relative to other providers.

On June 29, CMS announced that it would move forward with a demonstration project—the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI)—that will allow certain MA plans to be considered AAPMs for purposes of the new requirements established by MACRA.<sup>7</sup> This classification will allow physicians participating in MA plans that require providers to take on a certain amount of financial risk to be potentially exempt from the MIPS reporting requirements and allow them to earn a bonus under the AAPM payment system. This change is a welcome incentive for physicians to continue participating in MA plans, particularly given the evidence that beneficiaries with chronic conditions have better health outcomes and lower costs if they are enrolled in MA rather than traditional Medicare, even though MA enrollees have a higher proportion of clinical and social risk factors.<sup>8</sup>

### *Allowing Step-therapy in Part B*



On August 7, CMS provided MA plans greater flexibility in their benefit design and coverage of certain medicines. MA plans will now be able to impose step therapy requirements as a way to manage utilization of physician-administered drugs covered under the Medicare Part B benefit.<sup>9</sup> Step therapy is a utilization management tool in which patients are first required to try one treatment option before an insurer will cover a more expensive option; with respect to prescription drug coverage, this typically means first trying a generic or biosimilar medicine before a brand-name drug will be covered. It is hoped that this expanded authority will enable insurers to promote the use of higher-value medicines and to negotiate better discounts for drugs.

Specifically, CMS rescinded a memo from September 2012 that stated MA plans were not allowed to impose additional requirements (such as step therapy) that would hinder access to Part B drugs or services.<sup>10</sup> Additionally, joint MA-Part D plans will have new authority to cross-manage Part B and Part D drugs by allowing drugs covered under one benefit to be the first step of a treatment plan before allowing use of a drug covered by the other benefit. Any step therapy requirement must be coupled with drug-management and care-coordination services, and the beneficiary must receive at least half of the savings generated from reduced drug costs. These requirements are intended to encourage patient participation, which is essential to realizing better health management and medication adherence.

Although beneficiaries will still be able to request an exception to the step therapy requirement and appeal a denial, some patient advocacy groups are concerned that these tools could delay access to medications that a patient may need.

## Proposed Changes Not Yet Finalized

### *Site-Neutral Payments for Physician Services in FFS*

In a proposed rule published on July 25, CMS announced its intention to implement a site-neutral payment policy for services provided to fee-for-service (FFS) Medicare beneficiaries. Currently, Medicare pays different prices depending on where the same service is rendered, whether at an outpatient clinic owned by a hospital or in a physician's office or ambulatory surgical center.<sup>11</sup> The result will be about a 60 percent reduction in the reimbursement rates for hospital-owned outpatient clinics.<sup>12</sup> If these changes are finalized, beneficiaries



and taxpayers will stop overpaying for services simply because they are provided at a clinic owned by a hospital, saving Medicare patients an estimated \$150 million in 2019.<sup>13</sup> Just as with CMS's decision to [reduce reimbursements for drugs eligible for the 340B discount](#), non-Medicare patients and private insurers will also benefit long-term as this change will similarly lessen the incentive for hospitals to acquire physician practices, which drives up health care prices for all payers. (On that note, CMS has also proposed other changes to 340B that should reduce costs: extending its reduced reimbursement policy for 340B drugs to those provided at off-campus hospital sites, while simultaneously modifying the calculation of the average sales price (ASP) for non-passthrough biosimilars such that it is calculated solely based on the [biosimilar's ASP](#) rather than its reference product's.)

### *Resurrecting the Competitive Acquisition Program for Part B Drugs*

In the same proposed rule that proposed site-neutral payments, CMS included a request for information (RFI) regarding the Competitive Acquisition Program (CAP).<sup>14</sup> The CAP program was created in 2006 as an alternative means for providing coverage of drugs under Medicare Part B. Currently, when a physician administers a drug to a Medicare patient, these drugs are covered under the Part B benefit and physicians are paid 106 percent of the average sales price (ASP) of the drug. This payment structure encourages doctors to acquire the drug at the cheapest possible price. One wrinkle in this incentive structure, though, is the 6 percent add-on: Because the 6-percent add-on increases as the drug's price increases, this add-on can actually encourage the use of higher-priced drugs, increasing the cost for both Medicare and beneficiaries. The CAP program was created to mitigate this unintended consequence by removing physicians' financial interest in the administered drug. Instead of buying drugs themselves, physicians would acquire drugs for their patients through private vendors who would negotiate the price of the drug on their behalf and then bill Medicare. The program struggled to gain traction and low provider participation caused it to fade from existence after just two years. To learn from the program's past failures, CMS is seeking information on ways to reinstitute the program successfully as a new tool for negotiating lower drug prices.

### *Requiring Manufacturer Rebates and Price Concessions at the Point of Sale*



CMS similarly requested public feedback on a potential change to the way Part D plan sponsors handle drug rebates that are provided after the point of sale (POS).<sup>15</sup> The net price for prescription drugs is increasingly being determined by numerous rebates, discounts, and fees paid by or to drug manufacturers, pharmacy benefit managers (PBMs), insurers, and pharmacists after a patient has already picked up and paid their share of a drug's cost. In Medicare Part D, these post-POS rebates are typically classified as [direct and indirect remuneration](#) (DIR). CMS has noted that the value of DIR in Part D has been growing steadily, at an average annual rate of 14 percent per beneficiary per month between 2010 and 2015.<sup>16</sup> Because these rebates—which are often greatest for the highest-cost drugs, typically taken by the sickest patients—are paid after the patient has already paid their co-insurance, the beneficiaries typically do not benefit from the lower final price. As such, CMS is considering requiring Part D plans to pass on a portion of the estimated amount of the rebates at the POS to reduce beneficiaries' cost-sharing.

The Part D plans note that these discounts are instead used to reduce premiums, and argue that this policy change would lead to higher premiums for all beneficiaries. While this contention is true, it is estimated that the premium increase would be quite small, while the reduced OOP costs for beneficiaries taking high-priced drugs could be quite significant.<sup>17</sup> This change would restore an important insurance system design. The current system—by using the rebates provided by high-cost drugs to reduce everyone's premiums—results in the patients in poorer health subsidizing the healthier patients; this policy change would reverse that and make the insurance program work the way it should.

### *Increasing Risk-Sharing in Medicare ACOs*

Most recently, CMS issued a proposed rule that would reform the current structure and incentives of Medicare's various Accountable Care Organization (ACO) payment models within the Shared Savings Program.<sup>18</sup> These payment models have served, even before MACRA, as one of the primary ways in which CMS is working to reform the traditional Medicare reimbursement model so that providers are paid based on the value, rather than the number, of services they provide. The current service-volume focused model has led to the term "fee-for-service" (FFS).



The most fundamental aspect of the reforms just proposed (referred to as “Pathways to Success”) is the emphasis on transitioning ACOs into two-sided risk models in which they will not only be able to share in any savings generated but will also be responsible for a share of any costs incurred above a pre-determined benchmark. It is only when ACOs take on enough financial risk that they will qualify as AAPMs under MACRA.

Currently, the Medicare Shared Savings Program (MSSP) offers three tracks, with the first one not requiring participating ACOs to take on any shared financial risk, and the second and third requiring them to assume some. Not surprisingly, 80 percent of [ACOs](#) have enrolled and remained in Track 1, and some are generating losses, entirely at the expense of the Medicare program, while simultaneously benefitting from waivers of certain federal requirements as a result of their participation in the program. CMS believes these arrangements may be encouraging consolidation among providers and limiting competition, which significantly drives up health care prices.<sup>19</sup> On the other hand, those ACOs that have joined Tracks 2 and 3 and face financial liability for increased spending have produced significant savings and improved the quality of care provided. Given these findings, CMS is increasingly anxious to accelerate the move toward placing more financial risk on the providers.

The Pathways to Success design, the transition to which will begin in July 2019, will limit the number of tracks to two: a BASIC track (with five levels) where the risk will initially be zero but will gradually increase such that participating ACOs will eventually qualify as AAPMs, and an ENHANCED track, based on the existing MSSP Track 3.<sup>20</sup> The ENHANCED track provides participating ACOs the greatest opportunity for financial reward (and equal opportunity for financial loss) as well as additional tools, such as expanded coverage of telehealth services, and flexibility, such as a waiver to the rule that requires beneficiaries to spend three days in an inpatient hospital prior to being admitted to a skilled nursing facility.<sup>21</sup> While only high-revenue, experienced ACOs will initially be required to enter the ENHANCED track, eventually all ACOs will be.

## Conclusion

CMS’s goal is to transform the health care payment system, particularly through the Medicare program, to the extent that it can through the regulatory process. The reforms proposed or being implemented by CMS, though somewhat



incremental, should increase patient choice, realign incentives, and gradually reduce costs for both beneficiaries and taxpayers. The details of these initiatives will determine if they strike a fair balance between implementing downward price pressure for the taxpayer-funded program, and maintaining effective patient access to physicians and medications. Further, because of the size of the Medicare program, it often sets the path for the rest of the health care system. Thus, the changes being implemented by CMS are likely to have a broader impact beyond just the Medicare program and its beneficiaries.

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<sup>1</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-07179.pdf> (pg 151)

<sup>2</sup> <https://innovation.cms.gov/initiatives/vbid/>

<sup>3</sup> <https://www.law.cornell.edu/cfr/text/42/423.265> (The regulatory language uses the phrase “substantial differences” rather than “meaningful” and the statutory language does not appear to use either word in this context, but the industry stakeholders and CMS itself use “meaningful difference” when referring to this requirement, and thus AAF does as well for the sake of consistency.)

<sup>4</sup> <https://www.federalregister.gov/d/2018-07179/p-682>

<sup>5</sup> <https://www.federalregister.gov/d/2018-07179/p-2015>

<sup>6</sup> <https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program>

<sup>7</sup> <https://www.cms.gov/newsroom/press-releases/cms-advances-demonstration-waive-mips-requirements-clinicians-certain-risk-medicare-advantage-plans>

<sup>8</sup> [https://bettermedicarealliance.org/sites/default/files/2018-07/BMA\\_Avalere\\_MA\\_vs\\_FFS\\_Medicare\\_Report\\_0.pdf](https://bettermedicarealliance.org/sites/default/files/2018-07/BMA_Avalere_MA_vs_FFS_Medicare_Report_0.pdf)

<sup>9</sup> [https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA\\_Step\\_Therapy\\_HPMS\\_Memo\\_8\\_7\\_2018.pdf](https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf)

<sup>10</sup> [https://www.asrs.org/content/documents/cms\\_step\\_therapy\\_memo\\_091712-2.pdf](https://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf)

<sup>11</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf> (pg. 19)

<sup>12</sup> <https://www.healthleadersmedia.com/finance/site-neutral-payments-hospitals-unhappy-ops-2019>

<sup>13</sup> <https://www.cms.gov/newsroom/press-releases/cms-empowers-patients-and-ensures-site-neutral-payment-proposed-rule>

<sup>14</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf>

<sup>15</sup> <https://www.federalregister.gov/d/2018-07179/p-2041>

<sup>16</sup> <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>

<sup>17</sup> <http://phrma-docs.phrma.org/download.cfm?objectid=5F5FD190-AEDD-11E7-833F0050569A4B6C>

<sup>18</sup> [https://www.regulations.gov/document?D=CMS\\_FRDOC\\_0001-2459](https://www.regulations.gov/document?D=CMS_FRDOC_0001-2459)

<sup>19</sup> <https://docs.house.gov/meetings/IF/IF02/20180214/106855/HHRG-115-IF02-Wstate-GaynorM-20180214.pdf>

<sup>20</sup> The CMS rule and fact sheet capitalizes BASIC and ENHANCED, and given that these are programs in the health care industry, there seemed to be an extremely high probability that some ridiculous acronym existed, but it has been confirmed that these are in fact not acronyms.

<sup>21</sup> <https://www.cms.gov/newsroom/fact-sheets/proposed-pathways-success-medicare-shared-savings-program>