King & Spalding

Medicare Advantage: Regulatory Updates

A2HA Spring Meeting

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Topics

Medicare Advantage

- Increasing Share of Medicare beneficiaries
- April 2023 Final Rule
- Failure to Pay 340B Claims

Medicare Advantage Trends

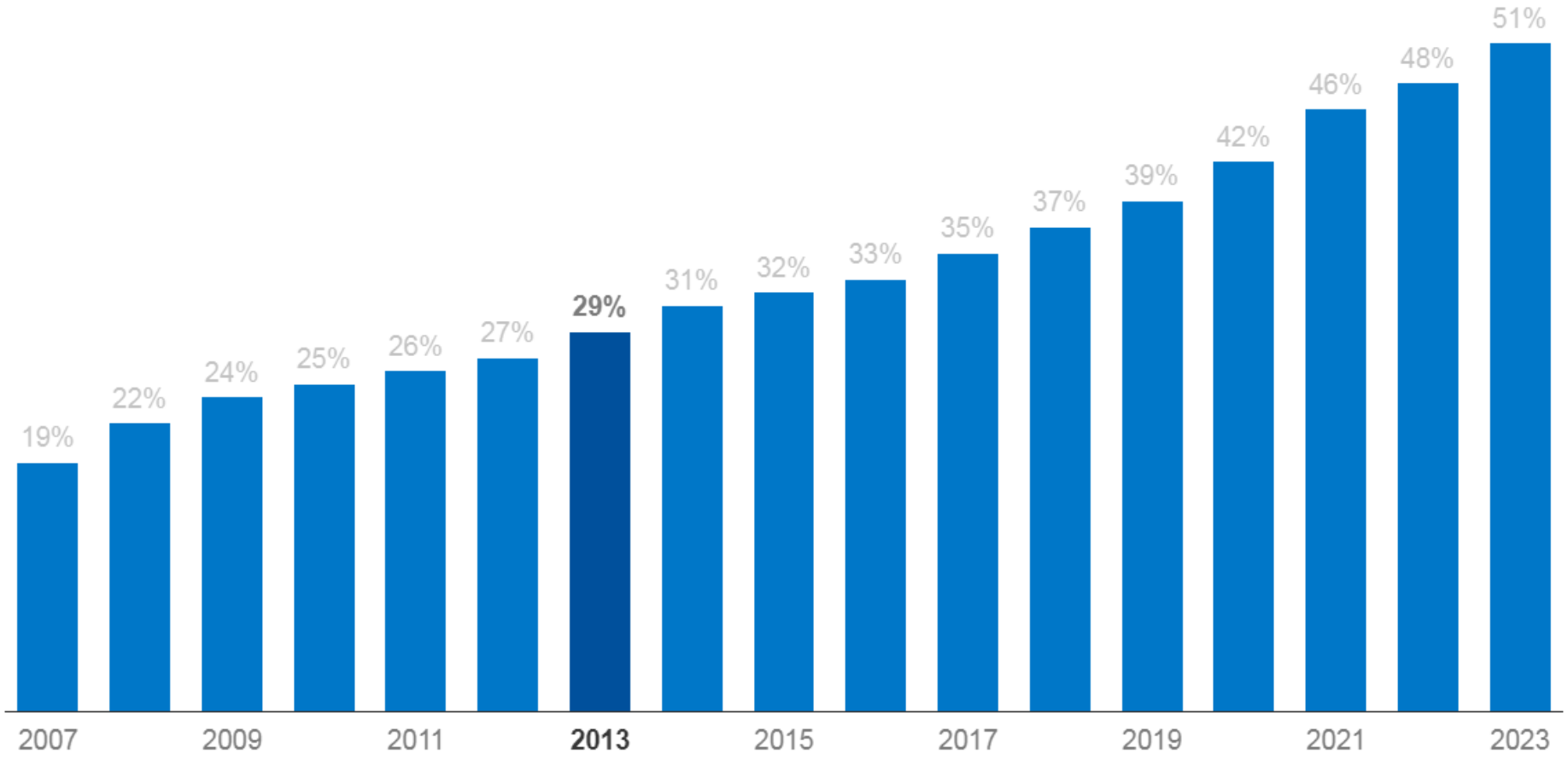
Over ***half*** of Medicare beneficiaries are in Advantage plans.

Representing **31 million lives …**

… and growing!

Total Medicare Advantage Enrollment, 2007-2023

Medicare Advantage Penetration | Medicare Advantage Enrollment



NOTE: Enrollment data are from March of each year. Includes Medicare Advantage plans: HMOs, PPOs (local and regional), PFFS, and MSAs. About 60.0 million people are enrolled in Medicare Parts A and B in 2023.

SOURCE: KFF analysis of CMS Medicare Advantage Enrollment Files, 2010-2023; Medicare Chronic Conditions (CCW) Data Warehouse from 5 percent of beneficiaries, 2010-2016; CCW data from 20 percent of beneficiaries, 2017-2020; and Medicare Enrollment Dashboard 2021-2023. •

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Medicare Advantage Enrollment by Firm or Affiliate, 2010-2023

	March 2010 Enrollment	March 2022 Enrollment	March 2023 Enrollment	Change in Number of Enrollees from 2022 to 2023
UnitedHealthcare	2,149,961	7,903,784	8,942,883	1,039,099
Humana	1,750,602	5,033,104	5,545,949	512,845
BCBS plans	1,648,307	4,053,286	4,350,123	296,837
CVS Health	624,208	3,105,056	3,322,716	217,660
Kaiser Permanente	953,300	1,796,616	1,847,966	51,350
Cigna	322,979	550,136	573,058	22,922
Centene	683,848	1,373,712	1,282,631	−91,081
All other insurers	2,621,701	4,597,203	4,887,976	290,773

NOTE: All other insurers includes firms with less than 2% of total enrollment. BCBS are BlueCross and BlueShield affiliates and includes Anthem BCBS plans (Elevance). Non-BCBS Elevance plans are 2% of total enrollment.

SOURCE: KFF analysis of CMS Medicare Advantage Enrollment Files, 2010-2023. • PNG

KFF

Hospitals are dropping Medicare Advantage plans left and right

Jakob Emerson - Updated Thursday, December 14th, 2023

The most cited reasons for cancelling MA plans:

1. Prior authorization denial rates
2. Slow payments from insurers
3. MA carriers are facing allegations of risk adjustment upcoding to increase Hierarchical Condition Categories that could put providers at risk and carriers are also being probed by lawmakers over their high billing denials.

BECKER'S Hospital CFO Report

Here are 13 more recent instances of hospitals dropping Medicare Advantage contracts:

1. In October, the Nebraska Hospital Association issued a report detailing how Medicare Advantage is "failing patients and jeopardizing Nebraska hospitals," 33% of which do not accept MA patients. The report cited negative patient experiences, post-acute placement delays, and administrative and financial burdens on hospitals that accept MA patients.

2. York, Pa.-based WellSpan Health will no longer accept Humana Medicare Advantage and UnitedHealthcare-AARP Medicare Advantage plans starting Jan. 1. UnitedHealthcare group MA PPO and Humana employer PPO MA plans will still be accepted.

3. Greenville, N.C.-based ECU Health said it anticipates it will no longer be in network with Humana's Medicare Advantage plans starting Jan. 1.

4. Raleigh, N.C.-based WakeMed went out of network with Humana Medicare Advantage plans in October. According to CBS affiliate *WNCN*, the plan provides coverage to about 175,000 retired state employees. WakeMed cited a claims denial rate that is "3 to 4 times higher" with Humana compared to its other contracted MA plans.

5. Zanesville, Ohio-based Genesis Healthcare System is dropping Anthem BCBS and Humana Medicare Advantage plans in 2024.

BECKER'S
Hospital CFO Report

MA Plans Profits Allegedly Drop

MA plans perceive that they are experiencing negative financial results.

This increases the odds that MA plans make dubious claim denial decisions and downcode visits.

Denials and Utilization Management Issues

2022 OIG Report: the Denials Problem

MAOs denied prior authorization requests for services that were medically necessary by applying MAO clinical criteria that are not contained in Medicare coverage rules

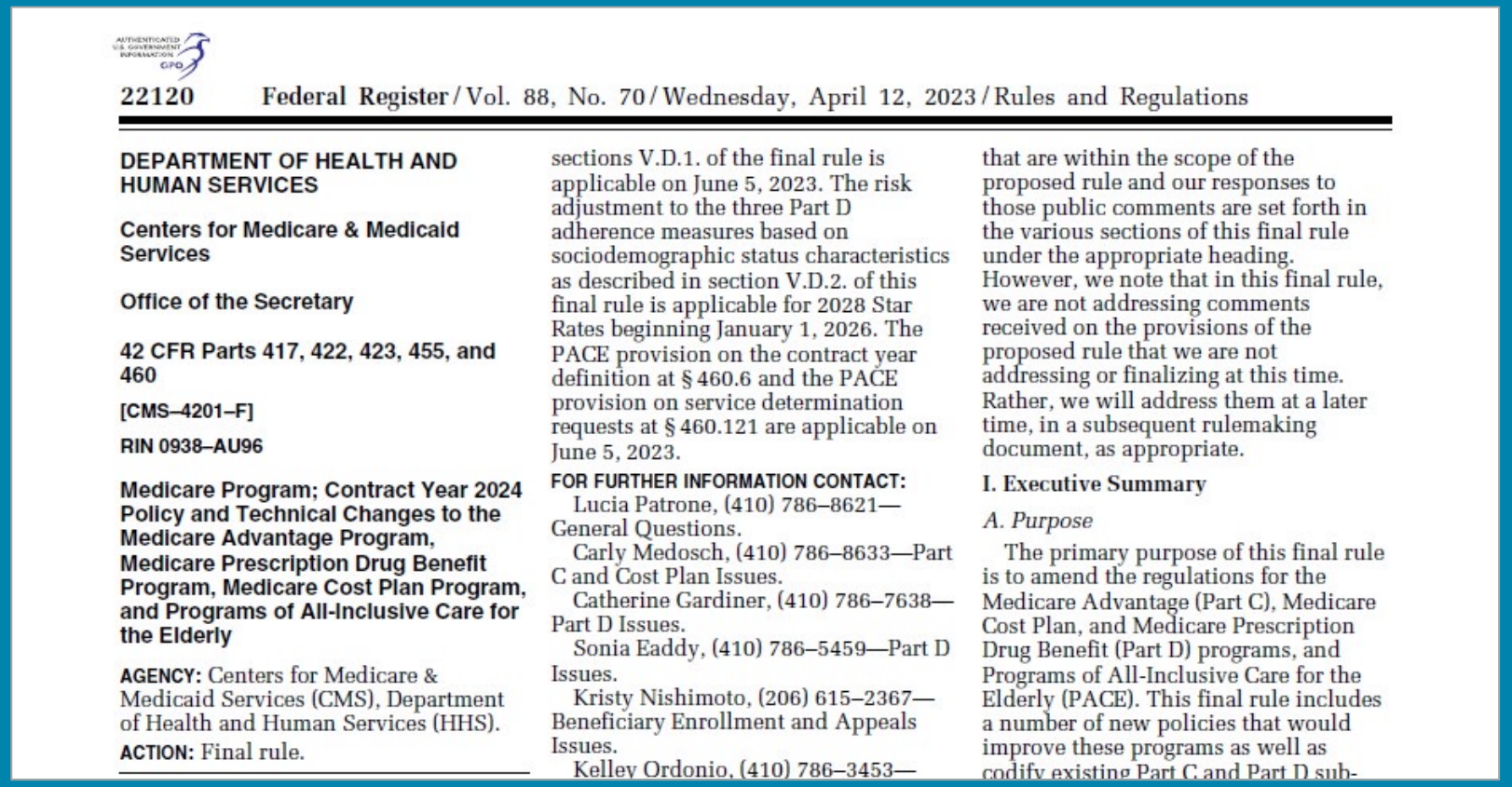
For many of the denials of prior authorization requests in our sample for services that met Medicare coverage rules, MAOs denied the requests by applying MAO clinical criteria that are not required by Medicare. As shown in the examples below, we found that in these cases MAOs used specific, mandatory requirements that resulted in the denial of prior authorization requests for medically necessary services. In contrast, original Medicare does not impose such specific requirements for covering the procedures involved. (For more detailed descriptions of all prior authorization and

2022 OIG Report: the Recommendation

Issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews

To help ensure that Medicare Advantage enrollees receive all medically necessary and covered services, to help promote MAO compliance with Medicare coverage rules, and to help improve program transparency, CMS should issue new guidance on both the appropriate use and the inappropriate use of MAO clinical criteria that are not contained in Medicare coverage rules. The guidance should clarify what the Medicare Managed Care Manual means when it says that MAO clinical criteria must not be "more restrictive" than Medicare coverage rules, and it should include specific examples of criteria that would be considered allowable and unallowable. CMS should also instruct MAOs to examine and revise their procedures for making coverage determinations, as needed, considering CMS's new guidance.

CMS Responds: Final Rule Published in Federal Register April 12, 2023



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Secretary

42 CFR Parts 417, 422, 423, 455, and 460

[CMS–4201–F]

RIN 0938–AU96

Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

sections V.D.1. of the final rule is applicable on June 5, 2023. The risk adjustment to the three Part D adherence measures based on sociodemographic status characteristics as described in section V.D.2. of this final rule is applicable for 2028 Star Rates beginning January 1, 2026. The PACE provision on the contract year definition at § 460.6 and the PACE provision on service determination requests at § 460.121 are applicable on June 5, 2023.

FOR FURTHER INFORMATION CONTACT:

Lucia Patrone, (410) 786–8621—General Questions.

Carly Medosch, (410) 786–8633—Part C and Cost Plan Issues.

Catherine Gardiner, (410) 786–7638—Part D Issues.

Sonia Eaddy, (410) 786–5459—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeals Issues.

Kelley Ordonio, (410) 786–3453—

that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule, we are not addressing comments received on the provisions of the proposed rule that we are not addressing or finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

I. Executive Summary

A. Purpose

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C), Medicare Cost Plan, and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). This final rule includes a number of new policies that would improve these programs as well as codify existing Part C and Part D sub-

Medicare Advantage (MA) Utilization Management

CMS's April 2023 Final Rule reaffirms long-standing policy that MA plans must follow Original Medicare coverage and adds provider and beneficiary protections against plan Utilization Management (UM) policies.

The Final Rule:

- ***Confirms*** MA plans must follow Section 412.3 standards for inpatient coverage ***and*** establishes stricter prior authorization requirements
- Imposes more rigor and transparency regarding the establishment of coverage criteria
- Requires more uniform and centralized MA plan oversight of UM programs

The Final Rule codifies ***existing*** policy that MA plans cannot provide lower coverage than Medicare ***and*** adds new requirements to ensure compliance. The new regulations will be effective on June 5, 2023, and apply to coverage beginning January 1, 2024.

MA Medical Necessity Coverage Criteria

Per CMS, its ***longstanding*** policy is that MA plans must make medical necessity determinations based on coverage criteria that are ***no more restrictive*** than coverage under traditional Medicare Parts A and B. This policy is based on the statutory requirement that MA plans cover items and services for which benefits are available under traditional Medicare.

CMS is amending the MA regulations to clarify that when an item or service has ***"fully established coverage criteria"*** under a National Coverage Determination (NCD), Local Coverage Determination (LCD), or traditional Medicare laws, an MA ***plan cannot impose any additional or different*** coverage criteria, processes or steps based on internal, proprietary, or external coverage criteria not contained in the traditional Medicare coverage requirements.

MA Medical Necessity Coverage Criteria

Coverage criteria *only* are considered not "fully established" when:

- Additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently,
- NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or
- There is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs.

A MA plan may not develop or rely on *internal* coverage criteria to make medical necessity decisions unless one of those three circumstances is present.

MA Application of the Two-Midnight Rule

The Two-Midnight Rule and Inpatient Only List applies to MA

CMS confirmed that MA plans are required to follow the:

- **Two-Midnight Rule** (when the admitting physician ***expects*** the patient to require hospital care that crosses two midnights)
- **Two-Midnight Case-by-Case Exception** (when the admitting physician does not expect the patient to require care that crosses two midnights ***but determines, based on complex medical factors documented in the medical record***, that inpatient care is nonetheless necessary.)
- **Inpatient-Only List**

MA plans are not required to follow the **Two-Midnight Presumption**, which is a ***separate*** CMS medical review instruction requiring traditional Medicare contractors to presume that hospital stays spanning two or more midnights after the beneficiary is formally admitted as an inpatient are reasonable and necessary for Part A payment.

Physician Documentation to Reduce Disputes, Avoid Improper Denials, and Improve Outcomes

Educate doctors to document their expectations when admitting.

Build check boxes and free text fields that quote from the language in 42 CFR 412.3(d).

Don’t paraphrase the regulation, it’s good as written.

- “(d) (1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.”
- “(i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.”

MA Medical Necessity Coverage Criteria

Any MA Plan internal coverage criteria must be based on current evidence in widely used treatment guidelines or clinical literature made available to CMS, enrollees, and providers.

A MA plan relying on internal criteria must provide an explanation that the coverage criteria:

- Is publicly accessible.
- Includes an identification of the general provisions that are being supplemented or interpreted.
- Includes how the additional criteria provide clinical benefits that are highly likely to outweigh clinical harms, including from delayed or decreased access to items or services.

Prior Authorization

MA Prior Authorization

The Final Rule Includes New Prior Authorization (PA) Requirements

1. **Purpose of PA Policies** — MA coordinated care plans may only use PA policies to confirm the presence of diagnoses and/or ensure medical necessity
2. **Duration of PA Approval** — MA coordinated care plan PA approvals must be valid for as long as medically necessary — CMS said this change was in response to evidence that MA plans often require repetitive approvals for needed services.
3. **90 Day Continuity of Care Time Period for New Enrollees** — CMS is establishing a 90-day continuity of care time period.

New CMS Guidance

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850

DATE: February 6, 2024

TO: All Medicare Advantage Organizations and Medicare-Medicaid Plans

SUBJECT: Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

New CMS Guidance

2. Question: Do the new rules on clinical coverage criteria for basic Medicare benefits mean that MA organizations cannot use algorithms or artificial intelligence to make coverage decisions?

An algorithm or software tool can be used to assist MA plans in making coverage determinations, but **it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made**. For example, compliance is required with all of the rules at § 422.101(c) for making a determination of medical necessity, including that the MA organization base the decision on the individual patient's circumstances, so an algorithm that determines coverage based on a larger data set instead of the individual patient's medical history, the physician's recommendations, or clinical notes would not be compliant with § 422.101(c).

New CMS Guidance

7. Question: Can an MA organization deny admission of a patient to a post-acute care facility from an acute care hospital if it's ordered by their physician and the patient meets the coverage criteria for admission into that facility?

Answer: No, if a patient is being discharged from an acute care hospital to a post-acute care facility that would be covered under Traditional Medicare and the patient's attending physician orders post-acute care in the specific type of facility (i.e., Skilled Nursing Facility (SNF), Long Term Care Hospital (LTCH)) and the patient meets all applicable Medicare coverage criteria for admission into that facility type, **the MA organization cannot deny admission to that post-acute setting and/or redirect the care to a different setting**.

340B Underpayments

Medicare Payments for Outpatient Drugs

Average Sales Price (ASP) Option

Two options for Medicare reimbursement rates for outpatient drugs:

- ASP Option
- Acquisition Cost Option

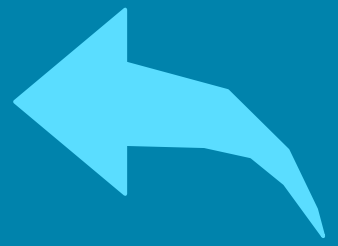
Historically, CMS selected ASP Option and set rate as **ASP + 6%** for all providers.

Effective January 1, 2018, CMS changed rate to **ASP - 22.5%** *for 340B providers only.*

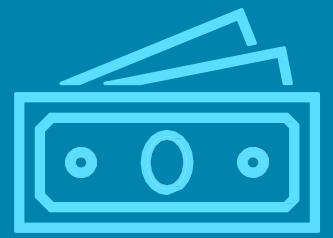
The *AHA v. Becerra* Decision

AHA and 340B providers challenge CMS rate in federal litigation

In June 2022, Supreme Court rules ASP - 22.5% unlawful and contrary to statute



On September 28, 2022, DC District Court vacates unlawful rate and reimbursement reverts to ASP + 6%



Issue of historical underpayments remanded to CMS

340B Final Rule Published November 8, 2023

Remedy for Unlawful 340B Cuts

One-time, lump sum payments totaling $9 billion to repay 340B covered entities.

Estimates 1,686 340B hospitals affected by unlawful cuts.

Did not provide instructions to Medicare Advantage plans.

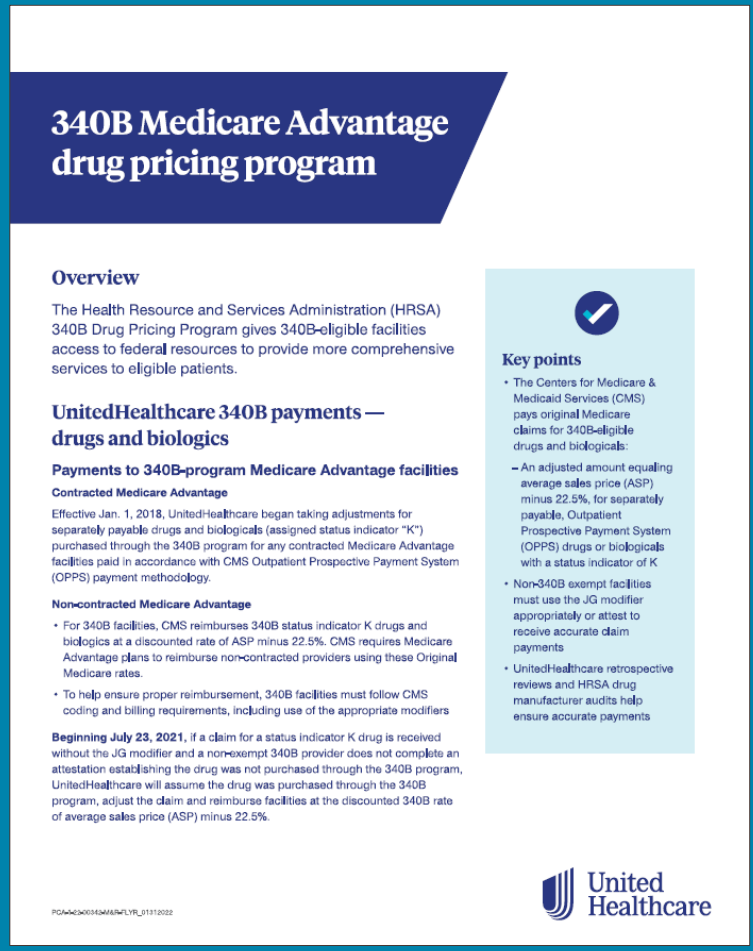
MA Plans Followed CMS's Discounts

Like CMS, MA Plans Underpaid 340B Drugs

From January 1, 2018 to September 27, 2022, MA plans paid for 340B drugs using a methodology that was based on ASP - 22.5%.

Rate determined to be unlawful in *AHA v. Becerra.*

In most instances, MA plans started paying corrected rate of ASP + 6% as of September 27, 2022 but refused to remedy historical underpayments.



340B Medicare Advantage drug pricing program

Overview

The Health Resource and Services Administration (HRSA) 340B Drug Pricing Program gives 340B-eligible facilities access to federal resources to provide more comprehensive services to eligible patients.

UnitedHealthcare 340B payments — drugs and biologics

Payments to 340B-program Medicare Advantage facilities

Contracted Medicare Advantage

Effective Jan. 1, 2018, UnitedHealthcare began taking adjustments for separately payable drugs and biologicals (assigned status indicator "K") purchased through the 340B program for any contracted Medicare Advantage facilities paid in accordance with CMS Outpatient Prospective Payment System (OPPS) payment methodology.

Non-contracted Medicare Advantage

- For 340B facilities, CMS reimburses 340B status indicator K drugs and biologics at a discounted rate of ASP minus 22.5%. CMS requires Medicare Advantage plans to reimburse non-contracted providers using these Original Medicare rates.
- To help ensure proper reimbursement, 340B facilities must follow CMS coding and billing requirements, including use of the appropriate modifiers

Beginning July 23, 2021, if a claim for a status indicator K drug is received without the JG modifier and a non-exempt 340B provider does not complete an attestation establishing the drug was not purchased through the 340B program, UnitedHealthcare will assume the drug was purchased through the 340B program, adjust the claim and reimburse facilities at the discounted 340B rate of average sales price (ASP) minus 22.5%.

Key points

- The Centers for Medicare & Medicaid Services (CMS) pays original Medicare claims for 340B-eligible drugs and biologicals:
  - An adjusted amount equaling average sales price (ASP) minus 22.5%, for separately payable, Outpatient Prospective Payment System (OPPS) drugs or biologicals with a status indicator of K
- Non-340B exempt facilities must use the JG modifier appropriately or attest to receive accurate claim payments
- UnitedHealthcare retrospective reviews and HRSA drug manufacturer audits help ensure accurate payments

United Healthcare

In Most Cases, MA Plan's Failure to Address 340B Underpayments is a Breach of Contract

Strength of Claim is Dependent on Contract Terms

Medicare rates are typically the basis for MA contract rates.

CMS's language in Final Rule was clear that the lump sum payments are an adjustment to the Medicare rate.

items and services budget neutralized. Because we are making adjustments to payments for CY 2018 through CY 2022, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)) requires us to make corresponding budget neutralizing adjustments to the "estimated amount of expenditures" for each of those years. To the extent necessary, this final rule can be viewed as a retroactive adjustment to the payment rates for each of 2018 through 2022, as authorized by section 1871(e)(1)(A) of the Act ((42 U.S.C. 1395hh(e)(1)(A)). We could have, for example, increased the payment rate for 340B-acquired drugs for CY 2018, and decreased the payment rate for non-drug items and services by 3.09 percent for CY 2018 and reprocessed all affected claims. While