Center for Medicare Advocacy
MedicareAdvocacy.org

The John A. Hartford Foundation

NATIONAL MEDICARE ADVOCATES ALLIANCE

ISSUE BRIEF #79 FEBRUARY 2023

MEDICARE ADVANTAGE UPDATES AND OTHER ISSUES[1]

I. MEDICARE ADVANTAGE UPDATES

There is consistent and growing evidence that Medicare Advantage (MA) plans are paid more on average than traditional Medicare for a given beneficiary, and such payments are causing significant challenges for Medicare's financial sustainability. At the same time, there is growing scrutiny of MA plans' use of prior authorization as a barrier to care for MA plan enrollees. As discussed below, the Centers for Medicare & Medicaid Services (CMS) recently released final and proposed rules that deal with MA payment, prior authorization, and other issues.

Final Audit Rule and Proposed Payment Rule

CMS recently released two important rules concerning Medicare Advantage payment issues: one concerning audits and recoupment of MA overpayments, and another outlining proposed MA payment for 2024. On February 3, 2023, the Center for Medicare Advocacy released an analysis of these policies in a document titled Center for Medicare Advocacy Statement on Recent Medicare Advantage Payment Policies and Proposals. The following is a summary of this analysis; for more information, see the full statement linked above.

MA overpayments stem, in part, from MA plans "upcoding" – reporting their enrollees as being more sick or requiring more intense levels of care than their medical records support in order to receive higher risk-adjusted payment. CMS has a process for auditing plan payments in order to recoup inappropriately paid dollars, called risk adjustment data validation (RADV) audits. This process, however, is years behind and a final rule updating the process has been long delayed.

On January 30, 2023, CMS released its long-awaited final rule regarding **Medicare Advantage (MA) Risk Adjustment Data Validation (RADV)**. In the Center's opinion, on the one hand, the final rule demonstrates CMS' acknowledgment of the need to address inappropriate MA overpayments, and it retains methodology strongly opposed by the insurance industry. On the other hand, CMS is leaving behind significant amounts of money that it has already determined were inappropriately paid over many years.

[1] Disclaimer: the views expressed in this Issue Brief and during the Alliance call are solely those of the Center for Medicare Advocacy.

On February 1, 2023, CMS released the **Calendar Year (CY) 2024 Advance Notice for the Medicare Advantage (MA) and Part D Prescription Drug Programs**, which includes proposed MA payment rates (the document is available here; also see CMS Fact Sheet here). Comments are due March 3, 2023. On the one hand, CMS appears to be taking steps to address overpayments by revising risk adjustment methodology to more accurately determine appropriate payment amounts. The proposed payment rate for 2024 would be a significant decrease from the more than 8% payment bump MA plans received in 2023 and the 4% increase they got in 2022. The insurance industry is already misleadingly characterizing this smaller increase as a "cut" to payment (and therefore a cut to benefits). On the other hand, CMS is not proposing to use its discretion to employ a higher coding intensity adjustment – described by the Commonwealth Fund as "an across-the-board cut [CMS] makes to plans' payments meant to adjust for the fact that some plans may be coding too intensely." CMS has the authority to adjust plans' payment more than the 5.9% statutory minimum, but it has so far not chosen to do so.

In our statement linked above, we note that, ultimately, Congress bears responsibility for setting Medicare payment and coverage policy. But despite some notable exceptions, most lawmakers do not even acknowledge, let alone try to address, Medicare Advantage overpayments, even when discussing the Medicare program's fiscal solvency.

Absent Congressional action, it is up to the Administration and CMS to act. The Center for Medicare Advocacy is encouraged by many of the steps taken by this Administration to increase oversight of MA plans and strengthen consumer protections (see, e.g., the discussion re: the Proposed Part C & D rule, below). When it comes to MA overpayments, however, it appears to be doing too little, too late.

We are very likely to see the insurance industry take steps to thwart implementation of the RADV rule, and to exert significant pressure on CMS to revise its proposed 2024 payment rates. We urge CMS to hold fast against this pressure, and to reinforce its efforts to rein in and recoup Medicare Advantage overpayments. The Medicare program, the people it serves, and taxpayers cannot afford any other course of action.

Prior Authorization and Coverage Denials

The Kaiser Family Foundation (KFF) noted in a report issued in 2022 that "nearly all Medicare Advantage enrollees (99%) are in plans that require prior authorization for some services" and that prior authorization is "most often required for relatively expensive services, such as Part B drugs (99%), skilled nursing facility stays (98%), and inpatient hospital stays (acute: 98%; psychiatric: 94%) and […] is also required for the majority of enrollees for some extra benefits".

More recently, the KFF issued a report titled "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021" (February 2023). The report analyzed the volume of MA prior authorization requests and approvals in 2021, and found that 6% of MA prior authorization requests were denied in full or in part. Overall, just 11% of denied prior authorization requests were appealed; of those that were appealed, 82% resulted in the initial denial being either fully or partially overturned. Kaiser noted:

> The high frequency of favorable outcomes upon appeal raises questions about whether a larger share of initial determinations should have been approved. Alternatively, it could reflect initial requests that failed to provide necessary documentation. In either case, medical care that was ordered by a health care provider and ultimately deemed necessary was potentially delayed because of the additional step of appealing the initial prior authorization decision, which may have negative effects on beneficiaries' health.

As discussed in previous *CMA Alerts*, including this one, the Department of Health & Human Services' Office of Inspector General (OIG) issued reports in recent years analyzing MA denials. OIG's 2018 report found "'widespread and persistent problems related to denials of care and payment in Medicare Advantage' plans". The report's findings included that when beneficiaries and providers appealed preauthorization and payment denials, MA plans "overturned 75 percent of their own denials." At the same time, "beneficiaries and providers appealed only 1 percent of denials to the first level of appeal." OIG issued another report in 2022 that analyzed denials issued by 15 of the largest MA plans during one week in June 2019. Among the prior authorization requests denied by MA plans, OIG found that 13 percent met Medicare coverage rules – "in other words, these services likely would have been approved for these beneficiaries under original Medicare". With respect to payment requests denied, OIG found that 18 percent met Medicare coverage rules and MA billing rules.

We routinely counsel Medicare beneficiaries who are inappropriately denied care, or have their care prematurely terminated, due to onerous MA plan utilization management techniques, including prior authorization. Such insurance practices are not limited to Medicare. The devastating impacts on individuals of prior authorization and coverage denials is poignantly highlighted in a recent *ProPublica* article titled "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings" by David Armstrong, Patrick Rucker and Maya Miller (Feb. 2, 2023). Although the article does not involve a Medicare Advantage plan, it exposes the unconscionable activities of the insurance company with the largest number of MA enrollees. Unfortunately, many of the prior authorization and coverage denial tactics used by insurers in non-Medicare settings are also used by the same companies in their MA plan offerings.

Fortunately, as discussed below, CMS is proposing to make significant improvements to consumer protections surrounding MA plans' use of prior authorization, along with other proposed changes that reflect the agency's recognition that certain inappropriate conduct of MA plans must be reined in.

Proposed Part C&D Rule Including MA Prior Authorization

As noted in this December 2022 *CMA Alert*, CMS released a proposed rule for Medicare Advantage and Part D for 2024 available here (87 Fed Register 79452, December 27, 2022). CMS also published a press release and accompanying fact sheet addressing the proposed rule. **Comments are due February 13, 2023**.

This proposed rule reflects CMS' intent to significantly improve consumer protections in a number of areas, including:

- Medicare Advantage Prior Authorization – among other changes, the rule would prohibit MA plans from denying coverage of a Medicare-covered item or service based on internal, proprietary, or external criteria not found in traditional Medicare coverage policies;
- Marketing of Medicare Advantage and Part D Plans – among other changes, the rule aims to crack down on misleading advertising, enhance requirements that agents and brokers explain coverage options, and better protect consumers from unwanted contact; and
- Enhance Access to Behavioral Health Services in MA Plans.

As discussed in the *CMA Alert* linked above, in December 2022, CMS published another proposed rule (87 Fed Reg 76238, December 13, 2022) that, among other things, would streamline prior authorization in Medicare Advantage, exchange, Medicaid and CHIP managed care plans. CMS also issued a press release and a fact sheet relating to the proposed rule. **Comments are due March 13, 2023.**

According to *Inside Health Policy* (Dec. 6, 2022), CMS says the proposed rule would save $15 billion over 10 years across all providers, and by some estimates "could significantly decrease the projected cost of the bipartisan MA prior authorization reform bill" (Improving Seniors' Timely Access to Care Act") – according to certain lobbyists, the rule could cut down the projected $16 billion cost of the bill by as much as half. The article notes that "[s]everal components of the related legislation – including implementation dates and certain timing requirements – align closely with CMS' proposed rule, which one lobbyist said is part of a two-pronged approach to ensure the process of revamping prior authorization is thorough." "Other aspects, however, are complementary."

As noted in the CMS press release and fact sheet announcing the proposed rule, most of the provisions would be effective in 2026, and include:

- Requirement that MA plans issue "decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests, which is twice as fast as the existing Medicare Advantage response time limit." CMS notes that they are "also seeking comment on alternative time frames with shorter turnaround times, for example, 48 hours for expedited requests and five calendar days for standard requests";
- Requirement that plans "include [a] specific reason when they deny a prior authorization request, regardless of the method used to send the prior authorization decision, to both facilitate better communication and understanding between the provider and payer and, if necessary, a successful resubmission of the prior authorization request"; and
- Requirement to "automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, as well as facilitate the exchange of prior authorization requests and decisions from their electronic health records (EHRs) or practice management system."

II. NURSING FACILITY UPDATE

In his State of the Union address on February 7, 2023, President Joseph Biden repeated his 2022 call for nursing home reform: "We're protecting seniors' life savings by cracking down on nursing homes that commit fraud, endanger patient safety, and prescribe drugs that are not needed."

A White House "FACT SHEET: The Biden Economic Plan Is Working" (Feb. 6, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/02/06/fact-sheet-the-biden-economic-plan-is-working/, released the day before the State of the Union Address, includes a statement about nursing homes:

> *Improving safety and accountability in nursing homes.* As the President directed in last year's State of the Union, CMS has taken action to strengthen oversight of the worst performing nursing homes, prevent abuse and Medicare fraud, and improve families' ability to comparison shop across nursing homes. In the coming days and months, CMS will announce new actions to increase safety and accountability at nursing homes.

White House announced important recommendations (Feb. 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/ But difficult to get them translated into enforceable policy.

Establishing and mandating nursing home staffing ratios, key recommendation. Report on what staffing levels are needed is done, but we have not seen it yet.

Nursing home industry is fighting, saying no one to hire, facilities need more money; also looking to extend temporary nurse aide program beyond the end of the public health emergency, to be able to train their own aides, and to change immigration law.

Nursing home advocates are countering, to the extent we can. E.g. "Nursing Home Residents Need Nurses, Wherever They Live" (CMA Alert, Feb. 2, 2023), discussing staffing needs and money exists in Medicare and Medicaid to pay for nurses.

Consumer Voice will be hosting series of webinars, beginning February 23, "Dignity for All: Staffing Standards Now."

Recent reports are critical and support advocates' call for change:

GAO, *Nursing Homes: CMS Should Make Ownership Information More Transparent for Consumer*, GAO-23-104813 (Jan. 2023):

The GAO finds that that *Care Compare* provides timely information about nursing home ownership, but does not meet the GAO's five other criteria for presenting meaningful data to consumers. The federal website is not written in plain language, does not highlight important patterns (e.g., chain ownership), is not easy to use, and fails to identify either the purpose and value of the information or the information's key strengths and limitations.

HHS Office of Inspector General, Data Brief, *More than a Thousand Nursing Homes Reached Infection Rates of 75 Percent or More in the First Year of the Pandemic; Better Protections Are Needed for Future Emergencies OEI-02-20-0048=91* (Jan. 2023):

Serious indictment of regulatory system, when 95% of these facilities (with 75%+ infection rates in 2020) met federal staffing standards and most were not cited with infection control deficiencies during targeted infection control surveys in the Spring and Fall of 2020.

OIG found "High COVID-19 transmission in a county did not always lead to nursing homes in that county reaching extremely high infection rates. . . . In other words, being located in a high-transmission county did not make it inevitable that a nursing home would have an extremely high infection rate," totally negating the nursing home industry's claim that there was nothing facilities could do if COVID-19 was in the community. Also see the Center for Medicare Advocacy's report *Geography Is Not Destiny: Protecting Nursing Home from the Next Pandemic*

HHS Office of Inspector General, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes*, OEI-07-20-00500 (Nov. 2022), found (1) 80% of long-stay residents took psychotropic drugs. 2011-2019; (2) substitution of psychotropic drugs (e.g., anti-convulsants) for antipsychotic drugs, 2011-2019; (3)facilities' falsification of resident assessment (MDS) data – "a 194% increase in the number of residents reported in the MDS as having schizophrenia but who lacked a corresponding schizophrenia diagnosis in their Medicare claims and encounters (2015-2019); (4) limited enforcement: 3,415 deficiencies for psychotropic drugs, but only 152 civil money penalties.

Some concern that changes called for by President's reform agenda are being undermined:

Antipsychotic drugs. CMS announced surveyor guidance in January that, for six months, will reduce star rating for quality measure domain to one star if off-site federal surveyors determine that facility miscoded diagnosis of schizophrenia.

Issues: (1) How much miscoding will be tolerated and not lead to downgrading of quality measure? CMS will not say. (2) CMS needs to cite deficiencies and impose penalties for miscoding, which it does not do now. CMS responds to only part of OIG report and *The New York Times* report in 2021 that "Phony Diagnoses Hide High Rates of Drugging at Nursing Homes."

III. IMPLEMENTATOIN of the INFLATION REDUCTION ACT (IRA)

As discussed in a previous *CMA Alert* (Aug. 18, 2022), President Biden signed into law the Inflation Reduction Act (IRA) of 2022 on August 16, 2022. This bill includes historic prescription drug provisions that are already providing significant benefits to Medicare beneficiaries. While some provisions will be phased in over the next few years, other provisions have already become effective in 2023.

Overview of IRA Prescription Drug Provisions

The following is a summary of the Medicare-related drug provisions in the IRA, to be phased in over the next several years. Note that the Part D changes also generally apply to Medicare Advantage plans that provide Part D prescription drug coverage, known as Medicare Advantage Prescription Drug (MA-PD) plans.

- Allows Medicare to **negotiate with drug manufacturers** for the price of some Part D and Part B drugs (starting in 2026);
- **Caps beneficiary out-of-pocket Part D drugs costs at $2,000** per year (starting in 2025 – also allows spreading of costs over course of the year, aka "smoothing"); in 2024, the 5% coinsurance for Part D catastrophic coverage will be eliminated);
- Imposes **checks on the annual rise in costs of drugs and Part D premiums** (limitations on drug prices start in 2023, and limitations on Part D premiums start in 2024);
- **Limits monthly out-of-pocket copays for insulin to $35** (starting in 2023);
- **Eliminates cost-sharing for adult vaccines** covered under Part D (2023); and
- **Expands access to the Part D Low-Income Subsidy** ("Extra Help") (starting in 2024) – full LIS up to 150% of the Federal Poverty Level (FPL) with higher resource limits.

For more information, see this CMS Fact Sheet "The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans" (Oct. 5, 2022), including a timeline and FAQ.

Changes in 2023

Insulin Copays Capped

Since **January 1, 2023**, **copayments for covered insulin products in Part D have been capped at $35 per month** (with no deductible). **Starting July 1, 2023, insulin furnished through durable medical equipment under Medicare Part B** (such as insulin pumps) **will be subject to the $35 per month cap** (note that the Part B deductible will apply before then). Note that Part D plans do not have to cover all insulin products at this copay level, only those insulin products that are on the plan's formulary.

Note re: Medicare Plan Finder and Insulin Copay Cap – because of when the IRA was passed relative to when Part D plans submitted their bid packages to the Medicare program for the 2023 plan year, the Medicare Plan Finder does not reflect the insulin copay caps, and will not do so throughout 2023 until 2024 plan information is posted. As a work-around, CMS suggests first doing drug searches without insulin in an individual's drug list, and add back in annual insulin costs ($35/mo x 12 = $420) to estimate maximum annual

drug costs. As a second step, do another search with the individual's insulin product and dosage to ensure it is covered by a given plan. (See, e.g, this CMS National Training Program flyer "Insulin Cost Sharing in 2023 Medicare Drug Plans", Oct. 2022.)

CMS has released both a **Fact Sheet** and an FAQ about the insulin provisions titled: **Frequently Asked Questions about Medicare Insulin Cost-Sharing Changes in the Prescription Drug Law** (Updated January 2023). Among other things, this FAQ discusses:

- Medicare Plan Finder issues as discussed above);
- A Special Enrollment Period (SEP) for Exceptional Circumstances for individuals "who use insulin who experience any issues or concerns" through the end of 2023; and
- Requirements for obtaining a reimbursement if an individual paid more than $35 for a month's supply of Part D covered insulin between January 1, 2023 and March 31, 2023.

No Cost-sharing for Vaccines Covered under Part D

Effective January 1, 2023, cost-sharing for vaccines covered under Part D are eliminated (even if an individual hasn't met the Part D deductible). This applies to adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), including the shingles and Tetanus-Diphtheria-Whooping Cough vaccines.

Other Drug Cost Changes

Rebates

Behind the scenes, other provisions of the IRA have become effective in 2023, including **checks on the annual rise in costs of drugs**. Under this provision, drug companies will be required to pay rebates to the Medicare program if prices rise faster than inflation.

On February 9, 2023, CMS issued initial guidance on how it will implement the drug inflation rebate program for Part B and D drugs, as described in this press release. CMS is seeking comment by March 11. In October 2022, the annual period for CMS to measure price increases of Part D drugs began; the period for measuring Part B drugs began in January 2023.

- View a fact sheet on the Medicare Prescription Drug Inflation Rebate Program guidance.
- Read the Medicare Part B Prescription Drug Inflation Rebate guidance.
- Read the Medicare Part D Prescription Drug Inflation Rebate guidance

According to *Bloomberg Law* (Feb. 9, 2023), "CMS estimates that starting April 1, people with Medicare may see lower out-of-pocket costs for certain Part B drugs and biologics with price increases higher than the rate of inflation. The beneficiary coinsurance for these drugs and biologics will be 20% of the inflation-adjusted payment amount, according to the CMS."

As highlighted in this previous *CMA Alert* (Jan. 19, 2023), a recent *New York Times* article titled "Medicare Begins to Rein In Drug Costs for Older Americans" by Paula Span (Jan. 14, 2023) (which quotes the Center for Medicare Advocacy) noted that "the Congressional Budget Office has estimated that this provision will save Medicare more than $56 billion over 10 years."

As outlined in a CMS press release (Jan. 11, 2023), if this provision "had been in place from July 2021 to July 2022, more than 1,200 prescription drugs potentially would have been subject to the new provision requiring

drug manufacturers to pay rebates to Medicare if they enact price increases that exceed inflation. Price increases on those drugs in the month the price change took effect averaged more than 30%."

Similarly, as recently highlighted in an update issued by the Campaign for Sustainable Rx Pricing titled "ICYMI: Study Finds Medicare Part B Would Have Saved $3.7 Billion Over Three Years if Big Pharma's Price Hikes Were Below the Rate of Inflation" an analysis published in the *Journal of the American Medical Association (JAMA)* found that "the Medicare Part B program would have saved $3.7 billion on prescription drug spending between 2018 and 2020" had this provision been in place during that time frame.

Negotiation

On January 11, 2023, CMS issued a memorandum titled "Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026" – also see accompanying press release. As noted in the press release, "For the first time in history, because of the Inflation Reduction Act, Medicare will have the ability to negotiate prescription drug prices. That process begins in 2023, and the first negotiated prices will go into effect in 2026." The memorandum outlines implementation steps, timelines, and public comment opportunities relating to the Medicare Drug Price Negotiation Program. A full timeline of the Drug Price Negotiation Program implementation process is available here: https://www.cms.gov/files/document/drug-price-negotiation-timeline-2026.pdf. As outlined in the press release:

Key dates for implementation include:

- By **September 1, 2023**, CMS will publish the first 10 Medicare Part D drugs selected for the Medicare Drug Price Negotiation Program.
- The negotiated maximum fair prices for these drugs will be announced by **September 1, 2024** and **prices will be in effect starting January 1, 2026**.
- In future years, CMS will select for negotiation 15 more Part D drugs for 2027, 15 more Part B or Part D drugs for 2028, and 20 more Part B or Part D drugs for each year after that, as outlined in the Inflation Reduction Act.

Coming Soon: Out-of-Pocket Caps

In a little over 10 months from now (starting in 2024), the Part D 5% coinsurance above the catastrophic level will be eliminated, effectively capping out-of-pocket costs, and the following year this cap will be lowered to $2,000.

IV. PUBLIC HEALTH EMERGENCY (PHE) UNWINDING

A Public Health Emergency (PHE) relating to the global COVID-19 pandemic has been in effect since January 2020. The PHE declaration has led to many changes in health care rules, including in the Medicare program (see, e.g., Center for Medicare Advocacy publication: **COVID-19: An Advocates Guide to Beneficiary Related Medicare Changes** (updated November 9, 2021). Also see, generally, Centers for Medicare & Medicaid Services (CMS) website at: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.

On January 30, 2023, the Biden-Harris Administration announced its intent to end the national emergency and public health emergency (PHE) declarations related to the COVID-19 pandemic on May 11, 2023.

Medicare

As noted in an *Inside Health Policy* article discussing **nursing home issues**, quoting the Center, "Nursing homes and beneficiary advocates are concerned that the conclusion of the COVID-19 public health emergency could restore a handful of controversial policies waived at the beginning of the PHE, including the three-day hospital stay and nursing aide staff training requirements" ("SNF Stakeholders Eye Return Of Pre-PHE Policies As Waivers Lapse" by Bridget Early, *Inside Health Policy* (Feb.10, 2023)).

Early notes that while "Both beneficiary advocates and nursing homes are concerned about the return of a three-day stay requirement [for SNF coverage …] Stakeholders are also focused on a set of temporary nurse aide training waivers, which are set to end at the conclusion of the public health emergency." The article states:

> The blanket nurse aide training waiver and TNA program began in March 2020 as part of the COVID-19 emergency response, when CMS waived requirements that nurse aides must receive 75 hours of training before providing care to nursing home residents. Nursing homes instead developed an eight-hour online training course for temporary nurse aides, who were meant to help with the COVID-19 emergency response, according to a brief from the Center from Medicare Advocacy.

The Center "is concerned that TNAs are likely filling gaps in facilities' certified nurse aide roster despite lacking the training to do so -- running the risk of both resident and aide injury and harm in the process."

A different *Inside Health Policy* article (Feb. 6. 2023) discussing **coverage of COVID-19 tests** notes that "CMS says Medicare beneficiaries will continue to have access to medically necessary laboratory-based COVID-19 PCR and antigen tests without cost-sharing after the end of the COVID-19 PHE, provided that the test is ordered by a physician or non-physician practitioner. However, CMS has repeatedly said that with the end of the PHE comes the end of Medicare coverage for at-home COVID-19 rapid tests."

Congress has expanded most of Medicare's **telehealth waivers** through the end of 2024. For a chart that outlines the telehealth flexibilities that have been extended, including through the Consolidated Appropriations Act, 2023, see, e.g., this McDermott+Consulting publication.

Medicaid

During the PHE, CMS implemented continuous coverage requirements and additional flexibilities to help individuals obtain coverage through, and stay on, Medicaid. These protections will soon be ending. As noted by an article in *Inside Health Policy* (Jan. 30, 2023):

> **Redeterminations.** Although the Medicaid redeterminations process was decoupled from the public health emergency by the Consolidated Appropriations Act of 2023, states are set to restart their normal redetermination processes as early as February. The continuous coverage requirement ends on March 31, and states can begin dropping Medicaid beneficiaries from coverage as soon as April 1.
>
> States have 12 months to begin redetermining each beneficiary's eligibility and 14 months to complete the process, but they're required to process fresh renewals for each beneficiary, meaning Medicaid staff can't use eligibility information obtained before February during the unwinding period.

Many of our national partners have developed and continue to put out **resources surrounding the PHE unwinding**. For example, see:

National Health Law Program (NHeLP): https://healthlaw.org/

- NHeLP PHE Unwinding Resource webpage

- Unwinding Medicaid Continuous Coverage: Checklist for Redeterminations (Feb. 2023)
- PHE and Continuous Coverage Unwinding Resources – a comprehensive list of PHE and continuous coverage unwinding guidance and resources (updated Jan. 2023)
- 10 Issues for Advocates to Monitor During the Medicaid Continuous Coverage Unwinding (Feb. 2023)
- Medicaid During and "After" the Pandemic: Changes that Should Become Permanent Policies (June 2021)

National Center on Law & Elder Rights (NCLER): https://ncler.acl.gov/

Justice in Aging: https://justiceinaging.org/

- Free Webinar: Unwinding of COVID Medicaid Continuous Coverage Requirements—What Advocates for Older Adults Need to Know Register Now
  When: March 2, 2023, at 11:00 a.m. PT/2:00 p.m. ET

V. LITIGATION UPDATE

- ***Johnson v. Becerra*, No. 1:22-cv-03024 (D.D.C.) (Challenge to Deprivation of Home Health Aide Services by Disabled Medicare Beneficiaries).** The Center for Medicare Advocacy filed this proposed class action on October 6, 2022, on behalf of three individuals and two organizations. The named plaintiffs seek to represent a nationwide class of Medicare beneficiaries who rely on home health aide services to live safely in their homes and communities. They challenge the Secretary's policies and practices that impede and restrict the availability, accessibility, and coverage of home health aide services for individuals with chronic, disabling conditions who qualify for such services under Medicare law. These practices include the failure to properly oversee and enforce Conditions of Participation for Medicare-certified home health agencies. They also include auditing and reviewing systems and quality rating systems that discourage the provision of aide services for plaintiffs and proposed class members. The case cites violations of the Medicare statute and regulations, as well as Section 504 of the Rehabilitation Act, which prohibits discrimination on the basis of disability. Section 504 imposes a duty on federal agencies to administer programs in the most integrated setting appropriate to the needs of people with disabilities and to avoid unjustified institutionalization of disabled people. The named plaintiffs and class members they seek to represent are at risk of institutionalization for necessary care without the Medicare-covered home health aide services they require. The plaintiffs seek declaratory and injunctive relief that would remove barriers to Medicare-covered home health aide services.

  UPDATE: The government filed a motion to dismiss on January 20, 2023 and Plaintiffs' opposition was filed on February 3, 2023. The government argued that the Plaintiffs do not meet the causation and redressability requirements for standing, and that Plaintiffs did not complete Medicare's administrative process. The government also claimed that Plaintiffs did not did state claims for violations of the Medicare or Rehabilitation Acts. Plaintiffs' opposition describes how they have plausibly alleged causation and redressability, that all Plaintiffs have presented claims to the Secretary and that exhaustion of Medicare's administrative remedies should be waived. Plaintiffs also explained that they have stated valid claims under the Medicare Act and Section 504 of the Rehabilitation Act. This includes the claim that the Secretary has an affirmative duty under the "integration mandate" of the Rehabilitation Act to administer programs in the most integrated setting appropriate to the needs of disabled beneficiaries. The government's reply memorandum is due February 15, 2023. Plaintiffs expect to file a motion to certify the class in the next few weeks.

- ***Barrows v. Becerra,* 24 F.4th 116 (2d Cir. 2022) (Beneficiary Appeals of Observation Status)**. In November 2011, the Center for Medicare Advocacy and Justice in Aging filed a class action lawsuit on behalf of individuals who have been denied Medicare Part A coverage of hospital and nursing home stays because their care in the hospital was considered "outpatient observation" rather than an inpatient admission. When hospital patients are placed on observation status, they are labeled "outpatients," even though they are often on a regular hospital floor for many days, receiving the same care as inpatients. Because patients must be hospitalized as inpatients for three consecutive days to receive Medicare Part A coverage of post-hospital nursing home care, people on observation status do not have access to nursing home coverage. They must either privately pay the high cost of nursing care or forgo that skilled care. The number of people placed on observation status has greatly increased as CMS has strictly enforced its definition of which services hospitals should bill as inpatient/Part A and which services they should bill as observation/Part B. However, CMS has not allowed beneficiaries to appeal the issue of whether their hospitalizations should be classified as observation or as inpatient for Medicare coverage purposes.

  After a dismissal by the district court, a remand by the Second Circuit, substantial motion practice and discovery, a bench trial on the merits of the due process claim was held in August 2019. In March 2020, the trial court issued a decision. ***Alexander v. Azar*, -- F. Supp. 3d --, 2020 WL 1430089 (D. Conn. Mar. 24, 2020)**. It held that the Secretary of Health and Human Services violates the Fifth Amendment Due Process Clause by not allowing certain patients to appeal their placement on observation status. Thus, as matter of constitutional due process, patients who are admitted as inpatients by a physician, but whose status is changed to observation by their hospital, have the right to appeal to Medicare and argue for coverage as hospital inpatients. In this ruling, the court held that there is a protected property interest in Medicare Part A coverage. The court did not, however, find a due process violation for patients whose doctors never order inpatient status, or whose status is switched only from observation to inpatient. It drew a distinction between the actions of doctors and the actions of hospital utilization review staff. The court modified the existing class definition accordingly.

  The court ordered that the agency establish an appeals process for class members, under which they can argue that their inpatient admission satisfied the relevant criteria for Part A coverage—for example, that the medical record supported a reasonable expectation of a medically necessary two-midnight stay at the time of the physician's inpatient order. Certain patients will be able to pursue these appeals in an expedited manner while still hospitalized. The court also ordered the agency to provide notice of these procedural rights.

  In May 2020, the government appealed the district court's trial decision to the Second Circuit. On January 25, 2022 the Second Circuit affirmed the trial court's decision in full. ***Barrows v. Becerra,* 24 F.4th 116 (2d Cir. 2022).** The court found that one of the named plaintiffs who paid over $10,000 for nursing home care after an observation stay had standing to sue. It found that decisions by hospital personnel to reclassify a patient from inpatient to an outpatient receiving observation services constituted state action. Finally, it conducted an analysis under *Mathews v. Eldridge* to agree with the trial court that the Secretary violates Due Process by offering no procedural protections for beneficiaries whose status is changed from inpatient to observation through the hospital utilization review process.

  The parties have conferred regarding implementation, and the district court has ordered the filing of status reports and held status conferences. The government is implementing the court's injunction via a Notice of Proposed Rulemaking. In September 2022, the government filed an estimated timeline for implementation,

as ordered by the court. It estimated that the Notice of Proposed Rulemaking will be issued in May 2023, with the public comment period ending July 2023.

In October 2022, the parties jointly requested a clarification of the judgment in the interest of facilitating and streamlining certain retrospective appeals and reducing administrative burden. The parties asked the court to clarify that if a class member who was enrolled in Part B at the time of their hospitalization prevails in appealing a retrospective claim, Medicare is not required to "unwind" and readjust the *hospital* claim, but may make Part A payment for the covered *nursing home* services without adjusting the underlying claim. On December 9, 2022, after a class notification process, the court issued an order clarifying the judgment as the parties had requested. Information about the clarification can be found here.

For answers to frequently asked questions from people who think they may be class members, please see the Center's website here.

- ***Hough v. Becerra*, No. 3:22-cv-06687-ZNQ-LHG (D.N.J.) (Off-label Part D Coverage).** On November 18, 2022, the Center for Medicare Advocacy and *pro bono* firm Murphy Orlando LLC filed suit on behalf of a retired public-school teacher in New Jersey who seeks coverage of her "off-label" (non-FDA-approved) use of a critically needed medication. Medicare denied coverage of the only medication that the beneficiary and her doctor have found to control her debilitating symptoms related to gastroparesis, a disease of the digestive system. However, the denial was based on an overly restrictive interpretation of what counts as a "medically accepted indication" under the law. After exhausting Medicare's appeal system, the plaintiff is now requesting review in federal court to receive coverage of the medically necessary treatment.

  The case is very similar to *Dobson v. Secretary of Health and Human Services*, 2022 WL 424813 (11th Cir. Feb. 11, 2022), in which the Center won coverage of the same drug for a Florida beneficiary. The *Dobson* court held that "support" for an off-label use means that an approved medical compendium that discusses the drug in question must tend to show or help prove the efficacy and safety of the beneficiary's prescribed use. Support does *not* mean that a compendium must "hyperspecifically identify" the prescribed off-label use of the beneficiary, as Medicare is requiring. The same reasoning should apply in this case.

  UPDATE: The government's response to the complaint is due February 17, 2023.

- ***Chinatown Service Center v. U.S. Dep't of Health & Human Servs.*, No. 1:21-cv-00331 (D.D.C.) (LEP Protections Under Section 1557 of the ACA).** Justice in Aging and the Center for Medicare Advocacy, along with *pro bono* firm Stinson LLP, filed this case on February 5, 2021 on behalf of two community-based organizations that provide social services to Limited English Proficient (LEP) older adults. In the waning days of the Trump Administration, the federal government eliminated protections for LEP individuals in health care by rolling back regulations that were put in place as part of Section 1557 of the Affordable Care Act. The protections were intended to target health disparities by requiring health plans and other entities to inform patients both of their right to interpretation, and their right to legally challenge discrimination based on language ability. But, in 2020, the Trump Administration issued a rule that eliminated these language access protections (as well as many others affecting LGBTQ people, immigrants, and women). The plaintiffs are asking the court to vacate the 2020 rule and enjoin its implementation.

  On October 13, 2021, the court issued an order staying the case until further notice while the Department of Health and Human Services revises the current Section 1557 rule. The court decided to follow the same

approach it had followed in a related case, *Whitman-Walker Clinic, Inc. v. HHS*, No. 20-1630, 2021 WL 4033072 (D.D.C. Sept. 3, 2021), which challenges several aspects of the 2020 rule, and in which the court had found that a stay was appropriate. The court also ordered HHS to provide bi-monthly updates on its proposed rulemaking. On July 25, 2022, HHS publicly released a proposed rule implementing Section 1557 of the Affordable Care Act. The proposed regulation was published in the Federal Register on August 4, 2022. On November 20, 2022, the government filed a status report noting that the public comment period on the proposed regulation closed on October 3, 2022, and that HHS had received more than 85,000 comments.

UPDATE: On January 31, 2023, the government submitted a status report stating that HHS's Office for Civil Rights is considering public comments on the proposed regulation.