

NATIONAL MEDICARE ADVOCATES ALLIANCE

ISSUE BRIEF #78

DECEMBER 2022

**RECAP of MEDICARE'S ANNUAL ELECTION PERIOD
AND OTHER ISSUES¹**

I. RECAP of MEDICARE ANNUAL ELECTION PERIOD (AEP)

The Medicare Annual Coordinated Election Period (AEP) – the period during which individuals with Medicare can make coverage choices for the coming year – ended last week on December 7th. During this time, people can enroll in, switch, or get out of Medicare Advantage (MA) and Part D prescription drug plans. They can also retain, or leave an MA plan, and enroll in traditional Medicare. Elections made during the period will be effective January 1st.

People who begin 2023 enrolled in an MA plan have an additional opportunity to switch MA plans or disenroll from an MA plan and return to traditional Medicare with a Part D plan during the first 3 months of the calendar year. This enrollment opportunity, called the Medicare Advantage Open Enrollment Period (MA-OEP), is not available to individuals who are in traditional Medicare and enrolled in a stand-alone Part D plan.

In addition, there are certain rights to use a Special Enrollment Period (SEP) to change or get out of a plan in certain circumstances. There are a number of SEPs, including when someone receives inaccurate or misleading information from the Medicare Plan Finder, customer service representatives at 1-800-MEDICARE, or an MA or Part D plan (or its agents). For a full list of available SEPs, see <https://www.medicare.gov/sign-up-change-plans/joining-a-health-or-drug-plan/special-circumstances-special-enrollment-periods>.

During the AEP (and, really, throughout the year) Medicare beneficiaries face an onslaught of insurance industry marketing materials aimed at convincing them to enroll in Medicare Advantage (MA) products, often using enticements of “extra” benefits. The deck is stacked in favor of Medicare Advantage plans and the insurance providers who sell them. Medicare beneficiaries face an onslaught of insurance industry marketing materials aimed at convincing them to enroll in a particular product(s) rather than encouraging informed decision-making about what options might be best for an individual. Rather than relying on enticements about the “extras,” or other sales efforts to enroll in a plan that is available from a particular broker, beneficiaries should make coverage decisions well-informed about the pros and cons of their coverage choices. In short, the public needs a balance, or counter-weight to insurance industry influence.

As discussed in recent CMA publications, including our “[Special Report | Recent Articles and Reports Shed Light on Medicare Advantage Issues](#)” (Oct. 31, 2022), we are hopeful about what we perceive to be an increase

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

in news coverage about Medicare, Medicare Advantage, and needed improvements that is more objective, and neutral. This AEP saw a number of articles and reports that highlighted various Medicare Advantage enrollment pitfalls, MA plan and agent/broker misconduct, access to care in MA plans, and other issues the insurance industry was not likely to promote this enrollment season, but about which beneficiaries should be aware.

Marketing Misconduct

In addition to more balanced articles and reports about the trade-offs between MA and traditional Medicare, there has been more attention of late on marketing misconduct, particularly surrounding the sale of MA plans. As discussed in the above-referenced report, this has included greater attention to the financial incentives of agents and brokers, including significantly higher commissions paid for MA enrollment vs. Part D and Medigap plans.

According to CMS earlier this year, beneficiary complaints about MA more than doubled between 2020 and 2021. Partly in response to this increase, on November 3, 2022, the Senate Finance Committee Majority Staff issued a report titled “[Deceptive Marketing Practices Flourish in Medicare Advantage](#)”. As noted in the accompanying [press release](#), the ‘report exposes numerous tactics used by insurance companies, brokers, and third-party marketers to push seniors to sign up for their plans, including deceptive mail advertisements, misleading claims about increasing Social Security benefits, aggressive in-person marketing tactics, and enrolling beneficiaries, particularly those dually eligible for Medicare and Medicaid, in a new plan without their consent.’”

As discussed in this CMA report: “[Senate Report Highlights Widespread Medicare Advantage Marketing Misconduct – But the Driving Forces of Misconduct Are Broader](#)” (Nov. 10, 2022), despite assertions of the insurance industry, the problem is much broader than a few “bad actors” or “outlier third-party marketing entities.” Instead, the Senate Finance report found a “consistent national picture” of fraudulent and misleading marketing practices that are “widespread, not isolated events.”

As stated in our report, we appreciate the insurance industry’s concerns about marketing misconduct. But what is driving these bad actors to do these bad things? Could the blame for misconduct be more broadly shared? **Is it not possible that major drivers of marketing misconduct include systemic problems motivated by the massive financial incentives for insurance companies to maximize enrollment in their most profitable products and, in turn, the corresponding incentives of those who sell these products?**

The Center strongly agrees with the policy recommendations made by the Senate Finance Committee, including reinstating requirements loosened during the Trump Administration, implementing robust rules around MA marketing materials and providing further support to State Health Insurance Assistance Programs (SHIPs). More fundamental and structural change is necessary, however, in order to truly right the Medicare ship. As the Center for Medicare Advocacy has long argued, legislative and administrative efforts are required to address the growing inequities between Medicare Advantage and traditional Medicare that favor MA, and thus encourage the growing privatization of the Medicare program. These inequities include overpayments to MA plans that unnecessarily drive-up programmatic spending, coverage expansions in MA only (such as supplemental or extra benefits) and inequities in enrollment opportunities (including limited federal guarantee issue rights to purchase a Medigap plan).

Medicare Materials

During the last Alliance call, we discussed the *Medicare & You* 2023 Handbook and CMS’ continuing effort to reverse bias towards Medicare Advantage. As discussed in a previous [CMA Alert](#) (Sept. 28, 2022), starting in the Fall of 2017, the Center for Medicare Advocacy (the Center) and other advocacy organizations began to highlight that, in a marked change from previous practice, the Trump Administration’s Centers for Medicare & Medicaid Services’ (CMS) outreach and enrollment materials actively promoted enrollment in private Medicare Advantage (MA) plans, while downplaying the drawbacks of such plans, and omitting key information. This included descriptions in the *Medicare & You* Handbook.

Last year, we were encouraged by the current Administration’s efforts to begin to reverse this trend of bias towards MA in the 2022 Handbook, as discussed in this 2021 Center [report](#). Earlier this Fall, CMS released the 2023 edition of *Medicare & You*, available [here](#). Based on our analysis of the 2023 version, we were pleased to see that the 2023 Handbook continues to improve with respect to eliminating bias towards MA by more accurately describing MA, including with respect to issues the Center flagged in the 2022 version. These changes help to restore the Handbook as an objective resource with accurate and unbiased information for Medicare beneficiaries. For further analysis, our [CMA Alert](#).

As discussed further in our “[Special Report | Recent Articles and Reports Shed Light on Medicare Advantage Issues](#)”, however, while many of the improvements made to *Medicare & You* have been incorporated in the comparison information and charts, there is also key information missing on the website, including relating to the prevalence of MA plan prior authorization.

Also of lingering concern, as noted in the above-referenced report, is that Medicare’s **email campaign** during the AEP was very “plan” focused – for example, a generic email sent on October 27, 2022 titled “What to consider when choosing your 2023 Medicare plan” encourages recipients to compare plans and then recommends factors to consider, most of which apply only to Medicare Advantage plans, and implies that one is already (or should be) in an MA plan, not traditional Medicare. Medicare also sent **targeted emails** to individuals, using their name and zip code. For example, in late October, Medicare sent an email to a beneficiary, “Jane “, with the title, “Jane, see how many Medicare Advantage Plans are available in your area”. The Center has spoken with individuals, including people with extensive professional education, who, after being subject to such information from Medicare, are left with the conclusion that they have no choice but to enroll in an MA plan. These materials do not adequately inform people that if they are in traditional Medicare, they can stay there, and if they have a stand-alone Part D plan, they can compare such plans for the following year – they do not need to enroll in an MA plan.

For additional information about Medicare Advantage, see, e.g., the Center’s website at <https://medicareadvocacy.org/medicare-info/medicare-advantage/>; also see our recent CMA webinar: [Medicare Advantage Overview & Concerns](#). Originally presented Thursday November 17, 2022 and sponsored by California Health Advocates Senior Medicare Patrol, this presentation addressed Medicare Advantage issues and concerns, and included an SMP fraud update.

II. MEDICARE ADVANTAGE OVERSIGHT

MA Prior Authorization – Bill and Proposed Rule

On September 14, 2022, the U.S. House of Representatives unanimously passed the “Improving Seniors’ Timely Access to Care Act” (H.R. 3173) which would streamline certain aspects of the Medicare Advantage prior authorization process. Among other things, the bill would establish an electronic “real-time” approval process for prior authorization requests concerning routinely approved items and services. In addition, the bill would accelerate MA organization determination deadlines (up to 24 hours for expedited appeals, 7 days for

standard appeals), boost MA plan’s data collection requirements, and in turn require the Medicare program to publish much of this data.

Around the time that the bill passed the House, the Congressional Budget Office (CBO) released an estimate that the bill would cost more than \$16 billion over 10 years. As noted by *Inside Health Policy* (Sept. 14, 2022), “CBO says it expects Medicare Advantage plans would increase their bids to include the cost of additional services, which would result in higher payments to plans.” The Senate has not yet taken up the bill, in large part due to the projected cost.

On December 6, 2022, CMS published a [proposed rule](#) (to be published in the Federal Register on 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. 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:

- A 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”;
- Require plans to “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
- A 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”.

III. MEDICARE PRESCRIPTION DRUG PROVISIONS in 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 will soon be of significant benefit to Medicare beneficiaries. While some provisions will be phased in over the next few years, other provisions will become effective next month, in January 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); 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

Starting **January 1, 2023, copayments for covered insulin products in Part D will be 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.

People who are charged more than \$35 per month for their insulin in early 2023 **may be reimbursed** (see, e.g., this CMS [memo](#) re: Part B drugs (Nov. 7, 2022)). In addition, in an unpublished FAQ (Oct. 2022), CMS has noted that it will be helping people who use insulin and who experience issues or concerns with their coverage, including choosing the wrong plan because they were unaware of the insulin cap, with a **potential Special Enrollment Period (SEP) opportunity** to change plans in 2023 (see, e.g., “[CMS Might Let Seniors Who Take Insulin Switch Plans Midyear](#)” by Gabrielle Wanneh, *Inside Health Policy* (Oct. 14, 2022).

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/\text{mo} \times 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.)

No Cost-sharing for Vaccines Covered under Part D

Effective January 1, 2023, cost-sharing for vaccines covered under Part D will be 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

Behind the scenes, other provision of the IRA 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. In addition, the first 10 drugs subject to Medicare negotiation (among the highest-spending, brand name drugs without competition), effective 2026, will be announced in 2023. CMS is expected to publish an initial list of 10 drugs subject to negotiation in September 2023. According to *Inside Health Policy* (Dec. 8, 2022), CMS has invited drug makers to the first of a series of sessions to discuss price negotiation this week (Dec. 13, 2022).

A little over a year 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. NURSING FACILITY UPDATE

Ownership and management of nursing homes have changed over the past 20 years. Key problems are: lack of transparency in ownership of nursing facilities; and lack of transparency, accountability of changes in ownership of real property.

The following issues are getting new public attention:

White House Nursing Home Agenda

Announced Feb. 28, 2022, includes multiple efforts to deal with ownership issues:

- Under heading Enhancing Accountability and Oversight, “Increase accountability for chain owners of substandard facilities”
- Increasing transparency, including “create a database of nursing home owners and operators; improve transparency of facility ownership and finances; examine the role of private equity”

See White House, “FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation’s Nursing Homes” (Feb. 28, 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/>.

Welltower and Integra

Welltower is a real estate investment trust; operates 147 nursing facilities in 15 states in a Joint Venture with ProMedica Senior Care. Recently, Welltower announced new Joint Venture with Integra to operate the facilities; rent to Welltower to increase 4%. Integra is a brand-new (months-old) unknown company, with no staff other than its CEO, David Gefner, who has no experience in health care.

See Harold Brubaker, “A new, unknown company gets key role at 38 Pa. nursing homes and 7 in N.J.,” *Philadelphia Inquirer* (Nov. 29, 2022), <https://www.inquirer.com/business/health/welltower-promedica-integra-nursing-homes-private-equity-ownership-20221129.html>, Hindenburg Research, “Welltower: Exposing The Shell Game” (Dec. 7, 2022), <https://hindenburgresearch.com/welltower/>.

People of the State of New York v. Comprehensive at Orleans LLC, Index No. ____ (NY Supreme Court, County of Orleans, filed Nov. 30, 2022)

Alleges “persistent fraud” and “repeated neglect and inhuman mistreatment” of residents at The Villages, upstate nursing home.

The New York Attorney General (New York Medicaid Fraud Control Unit) sued the nursing facility, Telegraph Realty (which owns the real property), CHMS Group LLC (which provides administrative services), ML Kids Holdings (“which received over \$1.5 million in cash transfers from Telegraph”), and “the sole official owner of The Villages, his three sons-in-law, his daughter-in-law; three undisclosed owners of The Villages; and the owners of Telegraph Realty LLC,” who diverted 22% of The Villages’ operating budget to themselves.

James’ Press Release says, “The owners wove a complicated web of fraud, using their ownership stakes in multiple companies to turn The Villages into a profit machine.”

In 2014, “the owners formed Telegraph for the sole purpose of buying the real property on which The Village sits, which they did a year later in January 2015.” Between 2015 and 2021, The Villages received \$86.4 million in funding, primarily from Medicare and Medicaid, \$18.6 million (22%) of which was diverted to the owners.

See New York Attorney General sues The AG’s Press Release is at <https://ag.ny.gov/press-release/2022/attorney-general-james-sues-orleans-county-nursing-home-years-fraud-and-resident>; the 152-page Complaint is at https://ag.ny.gov/Index/sites/default/files/orleans_nh_petition.pdf.

V. ORAL HEALTH UPDATE

Final Rule on Medicare Coverage of Medically Integral Dental Services

The federal Medicare statute excludes payment for dental services “in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth[.]”

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) issued a final rule (CMS-1770-F) that clarifies an exception to this exclusion for dental services that are “inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service.” Payment may be made under Medicare Parts A and B for such services when furnished in an inpatient or outpatient setting. CMS will codify this exception in its regulation at 42 C.F.R. § 411.15(i), along with examples of clinical scenarios where Medicare payment for dental services may be made under this exception. The specific scenarios recognized by the agency are:

- Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered organ transplant (including bone marrow and hematopoietic stem cell transplant for purposes of this policy), cardiac valve replacement, or valvuloplasty procedures; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with these procedures;
- Reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor;

- Stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints;
- Extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease

The rule provides that Medicare payment may also be made for ancillary services and supplies furnished incident to covered dental services, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

CMS did not find conclusive evidence to presently support payment for dental services in conjunction with immunosuppressant therapy, or joint replacement or other surgeries. However, the agency will amend its regulation and refine its policy to specify payment beginning in 2024 with respect to dental services needed prior to or contemporaneously with certain head and neck cancer treatment.

Of note, CMS expressly allows that regional Medicare Administrative Contractors (MACs) may appropriately determine, on a claim-by-claim basis, if payment can be made under the exception for dental services in other circumstances not specifically addressed by the finalized policies. Moreover, the agency is finalizing an annual review process by which CMS will consider public recommendations for this policy, as well as evidence submitted by interested parties to support the inclusion of additional clinical examples that qualify for coverage under the exception.

Coordination and exchange of information between a patient's medical and dental providers will be fundamental to Part B coverage and payment for dental services. Each provider would need to be enrolled in Medicare and meet all other requirements for billing (unless, alternatively, a non-enrolled dental provider performs services incident-to the professional services of a Medicare-enrolled physician who would submit the claim for payment). CMS states it will issue further guidance regarding enrollment, billing, compliance and other administrative matters for providers as needed.

VI. 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 disincentivize 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 provide services 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's response to the complaint is due January 20, 2023 and plaintiffs' motion to certify the class is due February 24, 2023

- ***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 proposed 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.

UPDATE: 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. The court ordered class counsel to notify the class of the proposed clarification, which they did by publication on their websites and through various emails lists and listservs from October 31 – November 30, 2022. On November 30, 2022, class counsel notified the court that no class members had expressed concerns about the proposed clarification. On December 9, 2022, 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.

- ***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.

UPDATE: 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.

VII. UPCOMING 10 YEAR ANNIVERSARY of *JIMMO* v. *SEBELIUS* SETTLEMENT

In 2011, the Center for Medicare Advocacy and Vermont Legal Aid brought the *Jimmo v. Sebelius* class action lawsuit on behalf of beneficiaries who were being denied Medicare coverage for skilled care on the basis that they were not improving or did not demonstrate potential for improvement (*Jimmo v. Sebelius*, No. 11-cv-17 (D.Vt.), filed January 18, 2011). **In 2013, the federal district court approved a settlement agreement that confirmed Medicare coverage should be determined by a beneficiary's need for skilled care, not the individual's potential for improvement; Medicare covers skilled care to maintain an individual's condition or slow decline.** Essentially, improvement or progress is not necessary as long as skilled care is required. The *Jimmo* standards apply to home health care, nursing home care, outpatient therapies, and, to a certain extent, for care in Inpatient Rehabilitation Facilities/Hospitals. See, generally, <https://medicareadvocacy.org/medicare-info/improvement-standard/>.

In order to acknowledge and celebrate the 10-year anniversary of the finalization of the settlement in *Jimmo*, the Center is asking stakeholders to send us stories of their successes with *Jimmo* – how *Jimmo* has brought individuals services and care they would not have otherwise obtained. Submit at Improvement@MedicareAdvocacy.org.