



A Presentation for HFMA
March 2025



Regulatory Lessons & Opportunities

AGENDA

- Review of 2024 Regulatory High-Points
- Landmark Case Discussion
- CMS Activity
- Financial Implications
- Updates Since December 2024

- Wrap-up Questions



2024 Regulatory Review

Highpoints



- April 2023 – CMS Final Rule 4201
(effective June 2023 *Fully Applicable January 2024*)
 - November 2024 – CMS *Proposed Rule* 4208
- January 2024 - CMS Final Rule 0057 (effective April 2024)
- August 2024 - FY 2025 IPPS (effective November 2024)
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CMS 4201-F

Medicare Advantage Plans Must Follow the Rules Too!

- “Our goal **to ensure that MA enrollees receive the same items and services as beneficiaries in the FFS program** is accomplished when the same coverage policies and approaches are used.
- We expect that MA plans will consult the **Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS guidance materials.**
- We note that **MA organizations must agree to comply with all applicable requirements, conditions, and general instructions under the terms of their contract with CMS** under § 422.504(a)” (emphasis added by author)

Source: <https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program>

(Pg. 210-211)



Key Takeaways

- Traditional Medicare Coverage Criteria Must be Adhered to as Primary Guidance;
- 2 Midnight Benchmark Rule Applies, but not the Presumption;
- The 3-day Qualifying Stay for SNF Services is Mandatory, Not Discretionary;
- External Coverage Criteria is Not Prohibited;
- Medical Necessity Reviews are Not Prohibited, so long as Medicare Coverage Criteria;
- Prior Authorization Reviews are Not Prohibited, BUT...
 - New limitations on use to prevent delays
 - 90-day validation
 - Separate rule will be issued to address new limitations



(Bonus) Proposed Rule

CMS-4208-P

- Released November 26, 2024 – Posted to the Federal Register December 10, 2024
- Comment Period Closed January 27, 2025
- *Expected* Final Rule – usu. within 60-days



- **Artificial Intelligence and Other Predictive Algorithmic Technologies**



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CMS 0057-F

Improving **Prior Authorization** Processes

Prior Auth Changes to review timeframes “create improve and shorten prior auth timeframes for certain payers (incl. Medicare and Medicare Advantage and Medicaid but NOT Qualified Health Plan issuers on the Federally-Facilitated Exchanges – ie. ACA marketplace). **NO LATER THAN 72HRS** for expedited (urgent) requests, or **7-calendar days** for standard (non-urgent) requests.

Note – the prior language said *provisional affirmations or non-affirmations* needed to be issued within 10-business days of receipt of the prior auth request or 2-business days is expedited



“When a doctor says a patient needs a procedure, it is essential that it happens in a timely manner,” said HHS Secretary Xavier Becerra. “Too many Americans are left in limbo, waiting for approval from their insurance company. Today the Biden-Harris Administration is announcing strong action that will shorten these wait times by streamlining and better digitizing the approval process.”



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FY 2025 Inpatient Prospective Payment Systems (IPPS) Rule



Payment Rates Increased by **2.9%**



Beginning November 1, 2024 CMS replaced the previous COVID-19 and influenza reporting standards for hospitals with a **new Condition of Participation (CoP)** reporting requirement



Beginning January 2026 CMS will be requiring hospitals in select CBSAs to participate in the Transforming Episode Accountability Model (**TEAM**):

- CABG
- Lower Ext Joint Replacement
- Major Bowel surgery
- Surgical Hips or femur fracture
- Spinal Fusion



Mandatory Participant Hospitals in TEAM



- Safety-net hospitals
- Rural hospitals
- Medicare dependent hospitals
- Sole community hospitals, and
- Essential access community hospitals

Exceptions:

1. Maryland-based hospitals
2. No TEAM-qualifying episode is initiated



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CY 2025 Outpatient Prospective Payment System (OPPS) Rule

CMS -1809-F

- Payment Rate Increased by 3.4% HOWEVER...reduced by .5% = 2.9%
 - *CMS argued they cannot increase the payment rates for OPPS greater than they did for IPPS*
- Narrowing the definition of “custody” to expand coverage to formerly incarcerated
- New Obstetrical Services CoP
 - 3 Phases Over 2 Years
- 3 medical procedures added to the IPO – 1 procedure removed



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CENTER FOR MEDICARE

Medicare Appeal Rights for Certain Changes in Patient Status Final Rule (CMS-4204-F) Fact Sheet

On October 11, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that establishes appeals processes for certain people in Traditional Medicare who are initially admitted to a hospital as an inpatient but, subsequently, reclassified by the hospital as an outpatient receiving observation services during their hospital stay, and who meet other eligibility criteria.

The final rule can be downloaded from the Federal Register at:
<https://www.federalregister.gov/public-inspection/current>.



Alexander v. Azar

March 2020



CASE HISTORY

[Alexander v. Azar](#) (Alexander): Although decided in Spring 2020, this landmark litigation began in November 2011 (orig. as Alexander v. Sebelius), filed by seven (7) Medicare beneficiaries on behalf of themselves and all Medicare beneficiaries considered deprived of Medicare Part A benefits because their hospital stays were later classified as observation.

Federal programs such as Medicare, are categorized as administrative because they are governed and regulated by government agencies – in this case, CMS. As such, challenges and appeals to agency decisions must follow administrative processes and are typically not found in the more traditional court system of litigation unless/until the administrative process is exhausted (ex. MAC to QIC to ALJ to DAB to FDC).

Uniqueness of Alexander – Although the care at the heart of this case involved skilled nursing services (typically covered by Medicare Part A), the challenge brought forth was not medical necessity, but rather whether these beneficiaries even had an administrative right to appeal.



“...filed by seven (7) Medicare beneficiaries...*deprived of Medicare Part A benefits...*”

In *Alexander*, the skilled nursing care of these Medicare Part A eligible patients was later (ie. after their SNF services already began) deemed *ineligible for Part A coverage* because their provider’s utilization review resulted in a CC44 status change from IP to OBS to ensure Medicare payment.

The status thereby changed their inpatient stay (incl. the 3-day qualifying stay) to obs, which in-turn negated their collective SNF Part A benefit eligibility. And before you ask...no, the two-midnight rule wasn’t even born yet (circa. 2013).

Though there is an expedited appeal process for patients to challenge the decision to discharge from inpatient care *before actual discharge*, and there is a standard administrative process to appeal the medical necessity of denied services, there was no process through which a Medicare Part A beneficiary could appeal a provider’s decision to change their status post-discharge. Nor is there a requirement to receive notice of same.



The core of this litigation was all about whether an individual has a protected interest in their health care benefits to the extent they should be given the right to challenge a decision that will impact those benefits. An argument that alleges a government agency (CMS) takes action to deprive an individual of a property interest without a fair opportunity to challenge is clearly a Constitutional violation that can ONLY be addressed by the Courts.

We The People...

The Constitutional Argument Was Born

And the Court in *Alexander* included a lengthy Constitutional analysis of a Medicare beneficiary's property interest in their benefits and thereby a Constitutional Right to Due Process.

The Court determined that although a beneficiary may not have a Constitutionally protected right to coverage per se, they do have a property interest in their benefits, which means they also have a right to weigh in on how those benefits are determined.

The Court ordered CMS to develop an administrative appeal process through which Medicare beneficiaries who were discharged as a hospital inpatient and later had their status changed to outpatient/observation.



Barrows v. Becerra

January 2022



The Department of Health & Human Services made good on their promise to appeal the ruling in *Alexander* last year, renaming the decades-long litigation to *Barrows v. Becerra* (*Barrows*). And the oral arguments for this appeal were finally heard by a Federal Appeals Court - on its last stop before SCOTUS - in the Fall 2021. HHS argued not only that these Medicare beneficiaries had no standing to appeal because they were not an appropriate “class” but they further challenged the lower court’s finding of a Constitutional violation.

On January 25, 2022 the Court in *Barrows* once again ruled in favor of Medicare beneficiaries and agreed that their due process rights were violated by the current administrative procedures. The Court opined that one of the most critical issues of the case is that a patient currently has no way to challenge a reclassification by a Utilization Review Committee (URC) from inpatient to outpatient, although they must receive notice of this status change (i.e., MOON).



Implications of the *Barrows* Ruling



As was the opinion in *Alexander*, the *Barrows* Court noted that although there is an appeals process for Medicare beneficiaries who face discharge from a hospital and a cessation of services (ie. the expedited appeals process per the MCPM Ch. 30, section 200), a similar administrative remedy is not available for those who have been reclassified as receiving observation for Medicare billing purposes.

Once again, CMS was ordered to create an administrative appeal process for these Medicare beneficiaries.

Next Stop

The BIG House



CMS *Proposed* Rule 4204 Highlights – December 2023

THREE New Appeal Processes:

1. Retrospective Appeals
2. Expedited Appeals
3. Standard Appeals

To conform with the appeals processes proposed, CMS also proposed the following:

- The delivery of a related appeals notice would be required as part of the Medicare provider agreement.
- The QIO regulations would be modified to specify that the QIO performs review functions for certain beneficiary appeals in a manner that is consistent with other QIO review functions while ensuring alignment with the proposed beneficiary eligibility and process requirements for such appeals.



CMS Activity December 2024

Original Medicare appeals

First Level of Appeal:
Redetermination by a
Medicare Contractor

Second Level of Appeal:
Reconsideration by a
Qualified Independent
Contractor

Third Level of Appeal:
Decision by Office of
Medicare Hearings and
Appeals (OMHA)

Fourth Level of Appeal:
Review by the Medicare
Appeals Council

Fifth Level of Appeal: Judicial
Review in Federal District
Court

CMS Rulings Issued Prior to
1995

Medicare Appeals Good
Cause for Late Filing

Hospital Appeals -Change of
Inpatient Status (Alexander v
Azar)

Hospital Appeals -Change of Inpatient Status (Alexander v Azar)

Medicare Appeal Rights for Certain Changes in Patient Status

A federal district court issued a judgment in the class action lawsuit, *Alexander v. Azar* (613 F. Supp. 3d 559 (D. Conn. 2020), aff'd sub nom., *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022), requiring the Centers for Medicare & Medicaid Services (CMS) to establish appeals processes for people enrolled in Original Medicare who are initially admitted to a hospital as an inpatient and subsequently reclassified by the hospital as an outpatient receiving observation services during their hospital stay and who meet other eligibility criteria.

On October 15, 2024, CMS issued a final rule implementing the court order. The final rule can be viewed at: <https://www.federalregister.gov/documents/2024/10/15/2024-23195/medicare-program-appeal-rights-for-certain-changes-in-patient-status>

New Patient Status Appeal

CMS has established two new appeals processes.

Beginning February 14, 2025, certain beneficiaries in Original Medicare who disagree with a hospital's decision to reclassify their status from inpatient to outpatient receiving observation services (resulting in a denial of coverage for the hospital stay under Part A) will be able to file for an expedited appeal prior to release from the hospital. More information on this process can be found at:

<https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative-bni/ffs-mcsn>

Beginning January 1, 2025, certain beneficiaries in Original Medicare will be able to file an appeal for denials of Part A coverage of hospital services (and certain skilled nursing facility services) resulting from a change in status from inpatient to outpatient receiving observation services made by the hospital. Eligible beneficiaries will be entitled to ask for appeals for hospital stays that began on or after January 1, 2009 through the implementation date of the prospective appeals process (February 14, 2025). The deadline for filing these appeals is January 2, 2026. This retrospective appeal process is detailed below.

February 14, 2025

January 1, 2025





New Appeal Process Highlights



Only beneficiaries have the opportunity to appeal;
THREE appeal opportunities – TWO Timelines

- Retrospective
- Concurrent Expedited
- Concurrent Standard

- Hospitals will be required to provide NOTICE - using the new *Notice of Status Changes and Appeal Rights* form;
- Hospitals will be required to ensure timely referral of any requested medical records;
- Favorable appeal decisions will result in hospital opportunity up to 365-days (1 year) after date of favorable decision;
- Instructions for submission of these claim resubmissions is still under development;
- Hospitals must make good attempt to deliver Notice, utilizing *assistive devices* where necessary.



Financial Implications



- CMS Final Rule 4204
 - New Appeal Process for Beneficiaries
- CY 2025 OPPS
 - 2.9% increase + New Obstetric CoP
- FY 2025 IPPS
 - 2.9% increase + New Acute Resp CoP + TEAM
- CMS Final Rule 0057
 - Prior Authorization Updates
- CMS Final Rule 4201 (and Proposed Rule 4208)
 - MAOs held to Medicare coverage criteria



Questions

