Healthcare Regulatory Roundup #111

Preparing for OBBBA Impacts:
Medicare DSH & 340B Updates

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Introductions



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Today's Agenda

1. Medicaid Community Engagement Requirements
2. Medicare Disproportionate Share Hospitals (DSH)
3. 340B Drug Pricing Program: Key Updates for 2026

1. Medicaid Community Engagement Requirements

Medicaid Community Engagement Requirements

- **Effective January 1, 2027:**
  - Adults aged 19–64 enrolled in Medicaid through the Affordable Care Act Medicaid expansion or equivalent coverage must complete at least 80 hours per month of paid employment, job training, education, and/or community service unless an individual meets a specific statutory exception.
  - At enrollment, a state must verify the individual met this requirement (or an exception) during the month prior to application; although, some states may require compliance for up to three months prior to enrollment.
  - Thereafter, a beneficiary's compliance must be verified every six months, but some states may require more frequent verification.
  - The time period for retroactive Medicaid coverage will be reduced from three months to one month.

Source: https://www.medicaid.gov/federal-policy-guidance/downloads/cib12082025.pdf

Medicaid Community Engagement Requirements (*cont.*)

- A comprehensive interim **final rule will be published by June 1, 2026**.
  - Shortly thereafter, states will be required to inform beneficiaries of these new requirements.
- A state may request an extension of the January 1, 2027, compliance date, but the request will not be granted unless the state demonstrates it is making a good faith effort to meet statutory requirements.



Community Engagement Requirements: Potential Impact

- Increased eligibility requirements for Medicaid coverage could result in:

Procedural disenrollments

Lower Medicaid patient volume

An increase in self-pay and uninsured volume

Lower Medicare DSH percentage

Potential loss of qualification of DSH add-on payments for some hospitals

Potential loss of qualification for 340B Drug Program discounts for some hospitals

Source: https://www.medicaid.gov/federal-policy-guidance/downloads/cib12082025.pdf

2. Medicare DSH

What Is Medicare DSH?

- Medicare Disproportionate Share Hospital (DSH)
  - Medicare makes additional payments to hospitals that serve a disproportionate number of low-income patients.
    - The additional payments are intended to offset the higher costs associated with providing care to these patients.
  - Different from Medicaid DSH, even though Medicare uses Medicaid-eligible days to determine eligibility.
  - Two types of Medicare DSH payments:
    - "Empirically justified" or traditional DSH
      - Driven by a hospital's Medicaid-eligible days and Medicare Supplemental Security Income (SSI) percentage
    - Uncompensated Care (UCC) DSH
      - Driven by a hospital's cost of uncompensated care (charity care and bad debt)
  - Traditional DSH percentage determines qualification for 340B drug discounts for many hospital types (some exceptions, such as Critical Access Hospitals), and this is the type of DSH we will discuss today.

Source: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/disproportionate_share_hospital.pdf

How Is the Medicare DSH Percentage Calculated?

- Disproportionate Patient Percentage (DPP)
  - The full Medicare DSH formula is complex, but there are two main drivers which form the DPP:
    - Medicaid Ratio (or Medicaid Fraction)
      - Percentage of total patient days attributable to patients eligible for Medicaid but **not** entitled to Medicare Part A coverage (Medicaid, non-Medicare days divided by total patient days)
    - Medicare Supplemental Security Income (SSI) Percentage
      - Percentage of total Medicare patient days attributable to patients entitled to both Medicare Part A (including Medicare Advantage patient days, patient days not covered under Part A, and days when patients exhaust their Part A benefits) and Supplemental Security Income (SSI)
        - SSI is a federal income assistance program administered by the Social Security Administration to adults and children with a disability or blindness and limited income, and adults aged 65+ without disabilities who meet certain financial qualifications
      - SSI percentage for each hospital is published by CMS based on CMS records
  - **DPP = Medicaid Ratio + SSI percentage**

Sources:
https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/disproportionate_share_hospital.pdf.
https://www.ssa.gov/pubs/EN-05-11002.pdf.

How Is the Medicare DSH Percentage Calculated? (*cont.*)

- DPP (Medicaid Ratio + SSI percentage) must be 15% or greater to qualify for Medicare DSH.
  - Example:
    - 1,000 Medicaid, Non-Medicare Days
    - 5,000 Total Patient Days
    - **Medicaid Ratio: 20%**
    - 200 Medicare Supplemental Security Income (SSI) Days
    - 2,000 Total Medicare Part A Days
    - **Medicare SSI Percentage: 10%**
  - From the example above, the **DPP is 30%** (the sum of the Medicaid Ratio and the Medicare SSI %).
    - Since the DPP is greater than 15%, this hospital qualifies for Medicare DSH (both empirically justified and UCC DSH).
    - However, the DPP is **not** the same as the DSH percentage; the DPP is used as the qualification threshold for DSH.

How Is the Medicare DSH Percentage Calculated? (*cont.*)

- **If the DPP (identified as "Threshold" to the right) is 15% or greater, the hospital qualifies for Medicare DSH, and the formulas, at right, apply:**
- There is also a Capital DSH payment that has its own formula.
- While the specifics are complex, the general idea is relatively simple. The higher the Medicaid Ratio and SSI percentage, the higher a hospital's DSH percentage.

Medicare DSH Payment Adjustment Formulas for Hospitals Qualifying Under the Primary Method

Status/Location	Number of Beds	Threshold	Adjustment Formula
Urban Hospitals	0–99 Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **Not to Exceed 12%**
Urban Hospitals	0–99 Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **Not to Exceed 12%**
Urban Hospitals	100 or More Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **No Cap**
Urban Hospitals	100 or More Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **No Cap**
Rural Referral Centers	N/A	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **No Cap**
Rural Referral Centers	N/A	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **No Cap**
Other Rural Hospitals	0–499 Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **Not to Exceed 12%**
Other Rural Hospitals	0–499 Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **Not to Exceed 12%**
Other Rural Hospitals	500 or More Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **No Cap**
Other Rural Hospitals	500 or More Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **No Cap**

Source: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/disproportionate_share_hospital.pdf

How Does the DSH Percentage Impact Hospitals?

There are two main impacts of the DSH percentage:

1

DSH add-on payments on each Medicare Traditional inpatient claim for qualifying hospitals

The higher a hospital's DSH percentage, the higher its add-on payment on each inpatient claim.

2

Qualification for 340B Drug Program

Most non-profit hospitals are required to meet a certain DSH percentage threshold to qualify.

Source: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/disproportionate_share_hospital.pdf

How Does the DSH Percentage Affect Reimbursement?

- Add-on payment to each Medicare Traditional inpatient claim:
  - 25% of the DSH percentage on Worksheet E, Part A, Line 33 of the Medicare Cost Report
  - Example:
    - DSH percentage on Worksheet E, Part A, Line 33 of **40%**
    - 25% of that number results in a **10% add on** to each Medicare Traditional inpatient claim
    - Claim payment before DSH was **$1,000**
    - 10%, or $100, DSH add-on for a **total claim payment of $1,100**
    - There would be an additional (smaller) Capital DSH add-on payment based on the following formula:
      - **[2.71828^(0.2025*DPP)]-1**
- **Higher Medicaid-eligible days ratio → Higher DSH % → Higher add-on payment on claim**

Source: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/disproportionate_share_hospital.pdf

Strategies to Accurately Report All Medicaid-Eligible Days

- Medicare SSI percentage is published by CMS based on internal records, on a delay.
- It is up to the provider to accurately identify and report all Medicaid-eligible days.

Use the Most Up-to-Date Medicaid Eligibility Data

- Wait as long as feasible to run the Medicaid eligibility lookups.
- A hospital will become ineligible for the 340B program on the day it files a cost report with a DSH percentage below the threshold.

Use Quality Demographic Data for Medicaid Eligibility Lookups

- To determine Medicaid eligibility, a hospital must submit patient demographic information.
- Providers should make every effort to ensure this information is accurate and complete.

Strategies to Accurately Report All Medicaid-Eligible Days (*cont.*)

Check Eligibility of Out-of-State Medicaid Patients

- Patients treated at a hospital outside of their home state may be classified by that hospital as a self-pay patient, as the patient's home state Medicaid may not pay for treatment outside of their state.
  - For Medicare DSH purposes, however, it matters only if a patient is eligible for Medicaid in a state, not whether Medicaid paid for a claim.
  - If a patient is eligible for Medicaid in their home state, the hospital can claim that patient as eligible for the DSH calculation, regardless of payment.

Evaluate Obstetrics/Psychiatric Departments

- Evaluate the impact that opening or closing high-Medicaid utilization departments could have on the Medicare DSH percentage.
- Medicaid-eligible days and total days from distinct part psychiatric units are excluded from the DSH calculation.

Strategies to Accurately Report All Medicaid-Eligible Days (*cont.*)

Accurate Matching of Newborns to Mothers

- When performing Medicaid eligibility lookups, newborns are considered eligible for the DSH calculation if their mother was eligible for Medicaid.
  - Hospitals should ensure they are matching newborns to Medicaid-eligible mothers to claim them as eligible.

Marketing to Medicaid Population

- While generally not a preferred strategy, hospitals that are close to the threshold may consider targeted marketing campaigns.

SSI Realignment



- The SSI percentage published by CMS is not up to date and often does not align with a hospital's fiscal year
  - The Federal fiscal year ends on 9/30
- SSI realignment could result in a higher DSH percentage and additional DSH add-on payments
  - However, it does not retroactively confer eligibility for the 340B Drug Program



340B Drug Program Qualification Thresholds

- DSH hospitals qualify with a DSH percentage greater than 11.75% (E, Part A, Line 33)
- Rural Referral Centers and Sole Community Hospitals qualify at a lower threshold of >=8.00%, but are subject to the orphan drug exclusion
- Children's Hospitals and Free-Standing Cancer Hospitals do not receive DSH payments, but must either have a DSH percentage >11.75% or a payor-mix equivalent
- Critical Access Hospitals do not have DSH requirements but have other requirements

Sources:
https://www.hrsa.gov/opa/registration/hospital-registration-instructions.
https://www.govinfo.gov/content/pkg/FR-2009-09-01/pdf/E9-21109.pdf.
https://www.340bhealth.org/members/340b-program/criteria-for-hospital-participation/.

3. 340B Drug Pricing Program: Key Updates for 2026

Changes to Child Site Registration

- **Albany Med Health System vs. HRSA (March 2026)**
  - U.S. District Court ruled there is no statutory requirement to register outpatient child sites.
  - HRSA is not authorized to impose new requirements creates additional opportunity for covered entities to recognize 340B savings in other outpatient settings.



Uncertainty Around the 340B Rebate Model Pilot Program

- Rebate model is a proposed shift from upfront drug discounts to a post-dispensing rebate system for specific drugs.
  - Under this model, covered entities purchase drugs at full cost and submit claims within 45 days of dispensing to receive rebates
  - Goal is to improve program integrity and prevent duplicate discounts
  - A U.S. District Court blocked the pilot of this model in February 2026, citing failure to follow proper procedural requirements, leaving the future of the rebate model in limbo
  - HRSA has been collecting input via Request for Information (RFI) to determine if a rebate model should be implemented and, if so, how it should be managed operationally – **comments due April 20, 2026**
  - **CEs are encouraged to submit feedback and can do so via this LINK**

2026 Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey

Hospitals reimbursed under OPPS must decide whether to respond to the CMS OPPS Drug Acquisition Cost Survey (ODACS) by **March 31, 2026**.

CMS will use ODACS responses to establish reimbursement rates for separately payable drugs (*including those acquired under 340B*).

Source: https://www.pyapc.com/insights/to-report-or-not-to-report-medicare-outpatient-drug-acquisition-cost-survey-odacs/

2026 OPPS Drug Acquisition Cost Survey (*cont.*)

- Section 1833(t)(14)(D) does not require hospitals to respond.
  - CMS is considering "reasonable assumptions" in the event a hospital does not respond, including how those assumptions might be reflected in that hospital's future payment rates.
  - Concerns around clarity of instructions for data submission, including methods for excluding purchases intended for inpatient use is requested.
  - Requires attestation to truth, accuracy, and completeness of submitted data; and adds that signer ***"acknowledge[s] that this attestation may be relied upon by CMS and other regulatory agencies for program integrity, reimbursement, compliance, and enforcement purposes. [The signer] understand[s] that knowingly providing false information may result in criminal prosecution, civil monetary penalties, exclusion from federal healthcare programs and other sanctions."***

Source: https://www.cms.gov/files/document/odacs-faq.pdf

Key Legislative Actions

In 2025:
19 states enacted 22 bills related to the 340B program and at least 13 states are considering actions in 2026.

- **Establishing pharmacy protections:**
  - Maine and Oklahoma now require that 340B-contracted pharmacies receive the same reimbursement as non-participating pharmacies.
  - Arizona prohibits third parties from imposing additional fees, assessments, or clawbacks on 340B-contracted pharmacies.
  - Rhode Island banned pharmacy network exclusion based on 340B participation.
  - In 2026, introduced bills include references to preserving a patient's choice to fill medications at a 340B-contracted pharmacy or directly from the participating 340B covered entity, or requiring manufacturers not to limit shipments of drugs to 340B-contracted pharmacies and covered entities.

Source: https://www.ncsl.org/state-legislatures-news/details/4-of-the-latest-trends-in-prescription-drug-legislation

Key Legislative Actions (*cont.*)

- **Prohibiting claims data requirements to receive rebates:**
  - To demonstrate program compliance, 340B pharmacies must report certain cost and pricing data to CMS, who sends this information to manufacturers.
    - Several manufacturers now require 340B covered entities to report claims data before providing 340B drug pricing discounts.
  - Supply chain entities in New Mexico and South Dakota may no longer require 340B claims or utilization data before providing reimbursement, with similar bills proposed in at least 11 states so far this year.



Source: https://www.ncsl.org/state-legislatures-news/details/4-of-the-latest-trends-in-prescription-drug-legislation

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Wednesday, April 22; 11 am – 12 pm ET

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