KHA's Federal Advocate
May 2, 2024

Federal Agencies Release New Rules and Guidelines

Proposed Rules Informational Webinar Available

As the federal government has released a flurry of rules this past month, below are a few informational webinars you or your staff may find valuable to participate in to get more information on one or all.

PYA is hosting a webinar at 10:00 a.m. on Wednesday, May 8, covering many of the recent rules from CMS and other federal agencies.

REGISTER HERE
PYA will discuss key provisions of the following proposed and final rules impacting health care providers:

- Fiscal year 2025 Hospital IPPS and Long-Term Care Hospital PPS Proposed Rule
- FY 2025 Hospice Payment Rate Update Proposed Rule
- FY 2025 Skilled Nursing Facility PPS Proposed Rule
- FY 2025 Inpatient Psychiatric Facility PPS Proposed Rule
- FY 2025 Inpatient Rehabilitation Facility PPS Proposed Rule
- Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting Final Rule
- Ensuring Access to Medicaid Services Final Rule
- Medicaid and Childrens Health Insurance Program Managed Care Access, Finance and Quality Final Rule
- Federal Trade Commission Non-Compete Clause Final Rule
- Department of Labor Overtime Pay Final Rule

Attendees will be eligible for 1.5 CPE credits in Specialized Knowledge.

CMS Releases IPPS Proposed Rule

On April 10, 2024, the Centers for Medicare & Medicaid Services released the federal fiscal year 2025 proposed rule for the Medicare Inpatient Prospective Payment System. The proposed rule reflects the annual updates to the Medicare fee-for-service inpatient payment rates and policies. In addition to the regular updates to wage indexes and market basket, key highlights include:

- IPPS overall rate change: +2.59 percent
- Uncompensated care payments to disproportionate share hospitals will increase by approximately $56 million.
- Proposed changes to core based statistical area delineations
    - 54 counties would change from urban to rural areas, and 54 would change from rural to urban areas.
- Proposal to continue the low Wage Index bottom quartile policy for at least three more years, beginning in federal fiscal year FFY 2025
        - Allows the wage data to stabilize following significant wage changes coming out of the pandemic. This will prevent the low wage index effects from being skewed.
- Separate IPPS payment for small, independent hospitals to maintain a buffer stock of essential medicines.
- Graduate Medical Education proposal to increase 200 new physician residency positions, half of those being in psychiatric beginning FFY 2026
- Request for Information – IPPS payment rates for maternity care by other payers.
- Changes to Hospital Consumer Assessment of Healthcare Providers and Systems measure for Inpatient Quality Reporting and Value-Based Purchasing programs.
- Transforming Episode Accountability Model proposed new mandatory model 2026-2030.
    - Would support patients with Medicare undergoing certain surgical procedures by promoting better care coordination, seamless transitions between providers and successful recovery.
        - Included procedures: lower extremity joint replacement, surgical hip femur fracture treatment, spinal fusion, coronary artery bypass graft and major bowel procedures.
- 200 CBSAs will be selected nationwide.
- Three tracks of financial risk

Program changes will be effective for discharges on or after Oct. 1, 2024, unless otherwise noted. CMS estimates the overall impact of this proposed rule update to be an increase of approximately $3.2 billion in aggregate payments for acute care hospitals in FFY 2025.

Comments on the proposed rule are due to CMS by June 10, 2024, and can be submitted electronically at http://www.regulations.gov by using the website's search feature to search for file code "CMS-1808-P."

DOL Finalizes Employee Overtime Pay Rule

On April 23, 2024, the Department of Labor released a final rule raising the salary thresholds for certain overtime exemptions under the federal Fair Labor Standards Act.

The rule is expected to result in approximately four million employees losing their exempt status under the FLSA. Therefore, employers must either raise the salaries paid to such employees to maintain the overtime pay exemption or reclassify their positions to non-exempt, paying them an hourly wage and overtime, where applicable.

The FLSA currently requires covered employers to pay employees minimum wage and overtime pay of at least 1.5 times an employee's regular rate of pay for those who work more than 40 hours in a week. Currently, an executive, administrative and professional employee making $684 per week, or $35,568 per year, can be exempt from the FLSA. The current minimum threshold to qualify for the white-collar highly compensated employee exemption is $107,432 per year.

Beginning July 1, 2024, this final rule will change those thresholds to $844 per week, or $43,888 per year, and the highly compensated threshold to $132,964 per year. Beginning Jan.1, 2025, this final rule will further raise the thresholds to $1,128 per week, or $58,656 per year, and the highly compensated threshold to $151,164 per year.

The salary threshold will be updated every three years, starting July 1, 2027.

CMS Finalizes Disproportionate Share Hospital Third-Party Payer Rule

The Centers for Medicare & Medicaid Services issued a final rule regarding the *Consolidated Appropriations Act of 2021,* which changed the hospital-specific limit on Medicaid disproportionate share hospital payments.

Specifically, Division CC, Title II, section 203 of the CAA 2021 (herein referred to as section 203) amended section 1923(g) of the Act, which describes the methodology for calculating hospital-specific Medicaid DSH limits. This rule will impact hospitals. The CAA 2021 modified section 1923(f) of the Act so reductions will occur from fiscal year 2024 through FY 2027, in the amount of $8 billion each year. Since Oct. 1, 2021, the amendments made by section 203 changed the methodology for calculating the Medicaid shortfall portion (Medicaid costs less Medicaid payments) of the hospital-specific DSH limit to only include costs and payments for hospital services furnished to beneficiaries for whom Medicaid is the primary payer.

Additionally, the CAA 2021 provides an exception for certain hospitals in the 97th percentile or above of all hospitals with respect to the number of Medicare Supplemental Security Income days. Those Inpatient days are made up of patients who, for such days, were entitled to Medicare Part A benefits and to SSI benefits or percentage of Medicare SSI days to total inpatient days.

HRSA Finalizes 340B Administrative Dispute Resolution Rule

On April 22, the Health Resources and Service Administration finalized its 340B Administrative Dispute Resolution rule. The 340B ADR process is an administrative process designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts or diversion, as outlined in statute. The ADR process is also designed to provide stakeholders the opportunity to have disputes evaluated in a timely, consistent, fair and equitable manner. This final rule revises the process to meet the stated goals. Key provisions of the final rule include:

- *ADR claims*. HRSA finalized definitions outlining the claims parties are permitted to bring to the ADR process. ADR may be used for claims by covered entities that have been overcharged and claims by manufacturers CEs violated prohibitions against diversion or duplicate discounts. HRSA further clarified overcharging includes claims a manufacturer has limited a CE's ability to purchase covered outpatient drugs at or below the 340B ceiling price. HRSA also finalized its proposals to require parties to file a claim within three years of the date of the alleged violation, and parties must engage in and document a good-faith effort to resolve the violation before using ADR.
- *Process.* Both the proposed and final rules reflect HRSA's commitment to ensuring the ADR moves away from a trial-like process to an administrative process accessible to all parties. HRSA is finalizing provisions to remove the use of the Federal Rules of Civil Procedure and Federal Rules of Evidence so covered entities, particularly those that are small or rural, do not need to hire outside counsel to navigate ADR. Additionally, the ADR process will use a panel of 340B experts from HRSA's Office of Pharmacy Affairs. Subject matter experts will have specific knowledge of the statute and operational processes of the program to successfully resolve disputes. When a claim is filed, the opposing party will have 30 days to submit a written response. HRSA noted in certain circumstances, such as missing key personnel, the ADR panel may exercise discretion in granting additional time.
- *Minimum threshold for ADR claims*. In response to National Rural Health Association's comment, HRSA is not including a minimum claim amount for parties to seek relief through the ADR process. HRSA reasoned many covered entities are small or rural providers in underserved areas, and ADR should be accessible regardless of the volume of purchases or sales.
- *ADR decision process*. HRSA did not finalize its proposal to suspend ADR claims if the same or similar issue is pending in federal court. In NRHA's comment, we advocated for

this change and are pleased with the final rule policy. Additionally, NRHA requested HRSA include a time frame for ADR panel decisions to provide certainty for covered entities, and HRSA finalized a provision requiring the panel to resolve disputes within one year.

- *Reconsideration process*. HRSA is largely finalizing the reconsideration process as proposed, with a modification suggested by NRHA to give parties up to 30 days, instead of the proposed 20, to file a request for reconsideration. Requests for reconsideration will be made to the HRSA Administrator and must include a copy of the ADR panel's decision and documentation as to why reconsideration is warranted. New facts and information may not be submitted. The Administrator will either issue a new decision or decline to reconsider the claim.

MEDPAC Sends Report to Congress on Medicare Payment Policy

The Medicare Payment Advisory Commission recently sent its annual March report on Medicare Payment Policy to Congress. The report covers several rural relevant issues such as Medicare Advantage, Rural Emergency Hospitals and recommendations to improve payment for clinicians and hospitals. You can access the report here.

Medicare Fee for Service Payment Adequacy and Updates

Congress requires Medicare Payment Advisory Commission to annually make payment update recommendations for providers paid under Medicare's traditional FFS payment systems. The goal of this update is to identify the base payment rate for each sector to ensure both beneficiary access and good stewardship of taxpayer resources.

Hospital inpatient and outpatient services

For federal fiscal year 2025, MedPAC recommends Congress increase base hospital payment rates for all hospitals and direct an enhanced pool of special payments to hospitals with high shares of Medicare patients, particularly low-income Medicare patients. Specifically, MedPAC recommends:

- Congress should update the 2024 Medicare base payment rates for general acute care hospitals by the amount specified in current law plus 1.5 percent. In addition, Congress should:
    - begin a transition to redistribute disproportionate share hospital and uncompensated care payments through the Medicare Safety-Net Index.
    - add $4 billion to the MSNI pool.
    - scale fee-for-service MSNI payments in proportion to each hospital's MSNI and distribute the funds through a percentage add-on to payments under the inpatient and outpatient prospective payment systems; and
    - pay commensurate MSNI amounts for services furnished to Medicare Advantage enrollees directly to hospitals and exclude them from MA benchmarks.

Physician and other health professional services

In 2022 and 2023, most clinician payment adequacy indicators remained positive or improved, but clinicians' input costs are estimated to have grown faster than the historical trend. Urban and rural Medicare beneficiaries reported comparable experiences and satisfaction levels on most questions, but there were observed differences between them in the mix of clinicians they saw.

- A higher share of rural Medicare beneficiaries reported receiving all or most of their primary care from a nurse practitioner or physician assistant at 29 percent compared with urban beneficiaries at 17 percent.
- A smaller share of rural beneficiaries reported seeing multiple specialists in the past year at 42 percent compared with urban beneficiaries at 55 percent. A smaller share of rural beneficiaries reported trying to find a new specialist in the past 12 months at 23 percent compared with urban beneficiaries at 34 percent.

MedPAC key recommendations to Congress include:

- For calendar year 2025, update the 2024 Medicare base payment rate for physician and other health professional services by the amount specified in current law plus 50 percent of the projected increase in the Medicare Economic Index
- Enact the Commission's March 2023 recommendation to establish safety-net add-on payments under the physician fee schedule for services delivered to low-income Medicare beneficiaries.

Skilled nursing facility services

MedPAC notes rural SNFs make up the minority of all SNFs at 27 percent, SNF stays and SNF spending. While not specific to rural SNFs, MedPAC found the supply of SNFs nationwide declined slightly in 2023 and stated this is likely related to a shift to home- and community-based care, low Medicaid reimbursement and patient preferences. MedPAC found Medicare margins for urban SNFs were one percentage point higher than rural SNFs. MedPAC also found indicators for payment adequacy for SNFs were positive. Thus, for FFY 2025, MedPAC recommends Congress should reduce the 2024 Medicare base payment rates for SNFs by 3 percent.

The Medicare Advantage Programs: Status Report

To monitor program performance, MedPAC examines MA enrollment trends, plan availability for the coming year, and payments for MA plan enrollees relative to spending for beneficiaries enrolled in traditional FFS Medicare. Key findings:

- Between July 2022 and July 2023, enrollment in MA plans grew by 8 percent—or 2.4 million enrollees—to 31.6 million enrollees.
- Between 2022 and 2023, MA enrollment rose from 49 percent to 52 percent of eligible Medicare beneficiaries.
- Enrollment patterns differ in urban and rural areas. The majority, 54 percent of eligible urban beneficiaries are enrolled in MA compared with 44 percent of eligible beneficiaries residing in rural counties. However, the growth of MA plans in rural areas has been much faster in recent years. In 2023, MA enrollment in rural areas grew by 12 percent compared with 8 percent growth in urban areas.
- Aggregate Medicare payments to MA plans have always been substantially higher than what estimated spending would have been in FFS Medicare.

MedPAC key recommendations to Congress include:

Replace the existing mandatory minimum coding intensity adjustment, which has reduced MA risk scores by 5.9 percent since 2018. There are three parts:

- develop a risk-adjustment model using two years of FFS and MA diagnostic data.
- exclude diagnoses documented only on health risk assessments from either FFS or MA,
- apply a coding adjustment fully accounting for the remaining differences in coding between FFS Medicare and MA plans.

The Commission also recommended the value incentive program address the variation in the demographics of MA enrollees across plans. By accounting for differences in enrollees' social risk factors by stratifying plan enrollment into groups of beneficiaries with similar social risk profiles, plans with higher shares of these enrollees would not be disadvantaged in their ability to receive quality-based payments, while actual differences in the quality of care would not be masked.

Mandated Report: Rural Emergency Hospitals

The first annual update on payments to REHs, the chapter provides context on the evolution of Medicare's support for rural hospitals and gives background on the REH designation and the hospitals that have converted to REHs. Overall, 21 hospitals converted to REHs. Before converting, these hospitals often furnished a low (and declining) volume of inpatient care, received enhanced payments from Medicare, were located relatively close to other hospitals, and had financial difficulties. The REH designation has been seen to overcome financial difficulties and retain local access to emergency and outpatient services in communities that cannot support a full-service hospital. MedPAC analyzed why the eight rural hospitals closed in 2023 did so instead of converting to REHs. Reasons identified include:

- Two hospitals are considering reopening as REHs, but they did not have time to convert prior to closure.
- One hospital became an outpatient facility of another hospital with a 24/7 emergency department but cannot convert to an REH because the state has not yet put REH regulations in place.
- One hospital converted to an outpatient department of a neighboring hospital owned by the same hospital system.
- One hospital is less than two miles from another Critical Access Hospital.

Three hospitals have more than 50 beds, making them ineligible to convert to REHs. Two of these hospitals are in the process of reopening as full-service hospitals.

MedPAC will continue to monitor the volume of hospitals transitioning to REHs, speak with representatives of rural hospitals considering converting, and analyze data to inform any future policy considerations. As part of ongoing monitoring, the Commission will consider possible modifications to the REH designation in the future.

CMS Finalizes Medicaid Access and Payment Managed Care Rule

The Centers for Medicare & Medicaid Services released April 22 a final rule focused on ensuring access to services for Medicaid and Children's Health Insurance Program beneficiaries in managed care delivery systems. The final rule is intended to increase transparency, improve accountability and ensure standardized data and monitoring, particularly for provider network adequacy requirements and state-directed payment programs. CMS also published an Informational Bulletin describing their plan to enforce provider attestation requirements beginning on Jan. 1, 2028.

Key Highlights:

Network Adequacy Metrics and Oversight:

- Establish maximum appointment wait times for primary care, obstetrics and gynecology services and substance use disorder services.
- Require states to use an independent entity to conduct secret shopper surveys to validate managed care plans' compliance with applicable standards.
- Require states to conduct an annual enrollee experience survey for each managed care plan.
- Mandate states to conduct an annual payment analysis for certain services compared to Medicare payment rates.

State Directed Payments:

- Require SDP levels for hospital, nursing and professional services at academic medical centers do not exceed the average commercial rate.
- Streamline the application and approval process for certain SDP programs.

- Prohibit the use of post-payment reconciliation processes for SDPs based on fee schedules.
- Make explicit in regulation the existing requirement SDPs must comply with all federal laws concerning funding sources of the non-federal share.
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CMS Finalizes Medicaid Access and Payment Fee-for-Service Rule

On April 22, the Centers for Medicare & Medicaid Services released a final rule focused on ensuring access to services for Medicaid beneficiaries in fee-for-service delivery systems in keeping with the Administration's objectives to improve access for Medicaid and Children's Health Insurance Program beneficiaries. The finalized provisions are intended to increase transparency, improve accountability and ensure standardized data and monitoring.

Key Highlights:

- Medical Advisory Committee and Beneficiary Advisory Group: Renames and expands the scope of states' Medical Care Advisory Committees and requires states to establish a Beneficiary Advisory Group. The MACs and the BAGs are intended to promote transparency and accountability amongst the state, stakeholders and Medicaid beneficiaries related to the effective administration of the Medicaid program.
- Fee-for-service Provider Payment Rate Transparency: Removes state access monitoring review plan requirements and replaces them with new payment rate transparency standards and documentation requirements. It also requires states to conduct a payment rate analysis for certain services every two years.
- Home- and Community-Based Services: Strengthens safeguards and provides for a more coordinated administration of policies and procedures for individuals receiving Medicaid-covered home and community-based services.

CMS Issues Final Rule for CY 25 Medicare Advantage and Prescription Drug Plans

On April 4, the Centers for Medicare & Medicaid Services released its final policy and technical changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Programs of All-Inclusive Care for the Elderly and Health Information Technology Standards for contract year 2025 (CMS-4205-F). The final rule includes a series of changes intended to strengthen beneficiary protections, promote access to behavioral health care providers, advance equity in coverage and improve supplemental benefits in the MA program. Specifically, the final rule finalizes requirements to:

- Strengthen network adequacy standards for certain behavioral health provider types.
- Streamline the appeals process for enrollees if the MA plan terminates coverage for certain post-acute care services.
- Lay the groundwork for increasing data collection and reporting from Part C and D plans.
- Annually review MA utilization management policies for health equity considerations

- Provide new guardrails for plan compensation to agents and brokers to prevent undue influence on beneficiary enrollment decisions.
- Ensure MA plans offer appropriate supplemental benefits.
- Simplify enrollment for individuals dually eligible for Medicare and Medicaid.
- Standardize the appeals process for MA Risk Adjustment Data Validation audit findings .
- Limit out-of-network patient cost sharing for certain plans serving dually eligible enrollees.
- Give Part D plans more flexibility to substitute biosimilars for reference drug products.

The Kansas Hospital Association hoped the calendar year 2025 MA rule would include greater direction or clarity around enforcement and compliance policies for the 2024 rules. KHA urges CMS to rigorously enforce and ensure plan compliance with the new rules finalized in this policy, as well as in the CY 2024 MA final rule, to ensure the important beneficiary protections included in both rules achieve their intended effects.

CMS Issues Final Eligibility and Enrollment Rule for Medicaid, CHIP and Basic Health Program

On March 27, the Centers for Medicare & Medicaid Services issued a final rule designed to streamline the eligibility and enrollment process for Medicaid and the Children's Health Insurance Program. This proposed rule is the continuation of efforts by CMS to improve access and coverage for the Medicaid and CHIP populations by removing enrollment barriers and reducing coverage disruptions for eligible individuals as state Medicaid programs conduct eligibility redetermination following the conclusion of the COVID-19-related continuous coverage period.

On March 27, the U.S. Department of Health and Human Services also concurrently released a new report highlighting the continuous eligibility requirements Congress passed in December 2022, which took effect Jan. 1, could protect as many as 17 million children from coverage disruptions.

Highlights of the proposed rule include:

- Prohibiting annual and/or lifetime limits on CHIP benefits. Currently CHIP regulations do not prohibit such limits, and several states have implemented them on CHIP benefits. The proposed rule would prohibit such limits consistent with existing prohibitions in the Medicaid program. The final rule also removes the state option to require a waiting period prior to CHIP enrollment.
- Allowing children covered by CHIP to remain enrolled or reenroll without a lockout period for failure to pay premiums. States currently have the regulatory option to impose a premium lockout period, which is a specified period a child or a pregnant individual must wait until being allowed to reenroll in the CHIP program after a certain period of non-payment of premiums. This policy change would align CHIP rules with those for the Medicaid program, which does not permit premium lockout periods.

- Establishing a clear process to prevent termination of eligible beneficiaries who should be transitioned between Medicaid and CHIP when their income changes or when the beneficiary appears to be eligible for the other program, even if the beneficiary fails to respond to a request for information.
- Clarifying states are permitted to establish an optional eligibility group for children with disabilities under age 21 whose eligibility is excepted from use of the Modified Adjusted Gross Income counting rules (e.g., for those living with a disability) or for other circumstances where such coverage is not already permitted in regulation.
- Requiring states to apply the same timeliness standard for renewal of enrollment as they do to initial applications. In addition, the rule would require states to allow sufficient time for beneficiaries to provide the documentation needed to retain enrollment (at least 15 days to return information related to an initial application and at least 30 days for information needed to retain enrollment). Finally, the rule provides states with options to use available information to update addresses when beneficiaries move within the state.
- Removing certain potential barriers to enrollment, such as requiring a person to apply for other benefits as a condition of Medicaid eligibility.
- Requiring states to conduct renewals no more than once every 12 months for those whose eligibility is based on being 65 or older, blind or disabled and prohibit requirements for in-person interviews for these populations. For these eligibility groups, states will also be required to use prepopulated renewal forms, provide a minimum 90-day reconsideration period after procedural termination, limit requests for information about a change in circumstances and accept renewals through multiple modalities.
- Includes a variety of program integrity provisions such as updating outdated recordkeeping regulations, removing regulatory references to outdated technology and establishing standards for retention of state records and case documentation.

FTC Non-Compete Final Rule Published

On Tue., April 23, 2024, the Federal Trade Commission issued a final rule banning non-compete agreements across industries nationwide subject to a few exceptions .The FTC approved the final Rule in a 3-2 vote. The rule becomes effective 120 days from publication in the *Federal Register*.

The rule bans current and future non-compete clauses in employment agreements. Non-compete clauses typically restrict workers from leaving a job to go to a competitor within a certain geographic area for a specified period.

The rule prohibits employers from entering into new non-competes after the effective date and from enforcing non-competes with workers, including more than just traditional W-2 employees except for certain senior executives:

- Non-competes in place prior to the effective date will still be allowed for “senior executives” defined as someone in a policy-making position earning more than $151,164 annually.

Once in effect, the rule prohibits covered employers from:

- Entering into or attempting to enter into non-competes
- Enforcing or attempting to enforce
- Representing a worker is subject to a non-compete

On or before the effective date, employers will have to provide workers with notice that the non-competes will not be enforced and cannot be enforced and otherwise meet the rule’s notice requirements.

The rule does not apply to certain categories of employers. More specifically, of interest to KHA members, the rule does not apply to non-profits since the FTC does not have jurisdiction over non-profit entities. The FTC indicated it reserves the right to evaluate a non-profit entity’s status to see if it is operating as a true non-profit and test whether it may fall under its jurisdiction.

The rule also does not apply to non-compete clauses entered into as part of a bona fide sale of a business interest.

The ruling has already been challenged, including a challenge by the United States Chamber of Commerce.