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State Laws Aimed at Artificial Intelligence Use in Health Care

AI legal landscape vastly different than a year ago, will be vastly different a year from now

By K. Tyler Dysart

Lawmakers, it turns out, are not feeling the same type of apathy as others when they see yet another article about artificial intelligence and its yet-to-be-seen impact on American lives and American businesses.

Health plans increasingly use AI for utilization management decisions, while providers turn to AI for administrative (or even clinical) assistance. A primary focus of lawmakers, therefore, has been not on ensuring Google's AI doesn't hallucinate fake idioms (such as, "never put a tiger in a Michelin star kitchen," as shared on Tom's Guide, <https://www.tomsguide.com/ai/google-is-hallucinating-idioms-these-are-the-five-most-hilarious-we-found>) or that attorneys refrain from using ChatGPT to write legal briefs [Maryland State Bar Association, Section on News, *Massachusetts Lawyer Sanctioned for AI-Generated Fictitious Case Citations*, https://www.msba.org/site/site/content/News-and-Publications/News/General-News/Massachusetts_Lawyer_Sanctioned_for_AI_Generated-Fictitious_Cases.aspx.] Instead, waves of legislation seen over the past year take aim at the use of AI throughout the health care system — from reviewing prior authorization requests to assisting (or even replacing) physicians in the care for patients.

And it is not just legislators using new laws to adapt to the changing landscape. Litigants are testing the changing landscape against existing federal, state and even common law (with varying degrees of success). In particular, patients and providers are testing the use of AI and other algorithmic systems in payer claim determinations or retrospective review under a variety of theories and causes of action, which could have impacts throughout the industry depending on the degree of litigants' success.

Yet, amidst the onslaught of new (and constantly changing) legislation attempting to keep up with new (and constantly changing) technology, the work of state senators and local representatives around the country nearly halted earlier this year. Sen. Ted Cruz proposed a so-called AI moratorium in the One Big Beautiful Bill Act, which was set to flex the muscles of the Supremacy Clause by restricting state AI regulation. Though the AI moratorium was removed from the bill that was signed into law, pushes for similar legislation or federal preemption permeate the federal government.

In July 2025, the Trump administration released America's AI Action Plan. The first issue addressed in the plan's first section: a call to "remove red tape and onerous regulation." [White House, *Winning the Race: America's AI Action Plan* (July 2025), <https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf>.] Thus, notwithstanding changes to the legal landscape around AI in health care to date, it is clear more are ahead.

State Legislation

Although many states have actively taken pen to paper to draft legislation seeking to address the use of AI in the health care industry, few have taken the same approach. Some states seek to wholly restrict AI use throughout the health care spectrum (from patient to provider to payer), while others simply require disclosure when AI is used. More states still have targeted specific uses of AI in health care, focusing on the use of AI in behavioral health care settings (and, more specifically, AI chatbots that purportedly exacerbate mental health symptoms).

States with generally applicable AI restrictions

Following is a recap of generally applicable AI restrictions in six states. The states include Arizona, California, Colorado, Maryland, Nebraska and Texas.

Arizona. On May 12, 2025, Arizona passed House Bill 2175, which was originally proposed by the Arizona Medical Association. The law is set to take effect on July 1, 2026, and addresses claim payment and prior authorization review by insurers. [Ariz. Rev. Stat. Ann. § 20-3103 (Supp. 2026); Ariz. Rev. Stat. Ann. § 20-3407 (Supp. 2026), <https://www.azleg.gov/legtext/57leg/1R/laws/0165.pdf>.]

The law requires that — before a health care insurer may deny a claim or issue a direct denial of prior authorization — a medical director must individually review the claim or request to “exercise independent medical judgment and may not rely solely on recommendations from any other source.” The question for purposes of compliance and enforcement would be the extent to which the medical director can rely on suggestions from artificial intelligence. It is clear medical directors cannot be absent from the decision, but the law also seems to allow the use of AI tools in their decisions (which is consistent with the approach of other states, noted below).

California. It should come as no surprise that California has numerous laws that would impact or curtail the use of AI in health care (and other industries). The landmark legislation aimed at health care, however, is what is known as the Physicians Make Decisions Act, signed into law by Gov. Gavin Newsom in September 2024. [2024 Cal. Stat. ch. 879 (S.B. 1120), https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240SB1120.]

The legislation was sponsored by the California Medical Association and broadly applies to prospective, retroactive and concurrent utilization management decisions made by health insurers. The law states that no person “other than a licensed physician or a licensed healthcare professional who is competent to evaluate the specific clinical issues involved in the healthcare services requested by the provider, may deny or modify requests for authorization of healthcare services for an enrollee for reasons of medical necessity.”

The law, however, also allows for physicians to use AI as long as certain conditions are met — such as basing decision-making on “individual clinical circumstances” and ensuring that AI does not “supplant healthcare provider decision making.”

Colorado. With an effective date delayed until July 1, 2026, Colorado’s expansive, 25-page Senate Bill 24-205 has been the subject of high scrutiny and is almost certain to have substantive changes before it goes into effect. The law is aimed not just at health care, but would impact nearly any commercial use of AI. [S.B. 24-205, 74th Gen. Assemb., 2d Reg. Sess. (Colo. 2024), https://content.leg.colorado.gov/sites/default/files/2024a_205_signed.pdf.]

The law is not aimed at prohibiting AI use by a physician or payer in decision-making, but, instead, focuses on disclosure. Specifically, entities are required to inform patients about the use of AI (including disclosure about chatbots), and require that developers and users of the technology have governance measures in place to prevent, among other things, “algorithmic discrimination.”

Maryland. Effective Oct. 1, 2025, Maryland’s approach to regulating AI is largely modeled after California’s. [2025 Md. Laws ch. 747 (H.B. 820), <https://mgaleg.maryland.gov/2025RS/bills/hb/hb0820T.pdf>.] As such, it

requires oversight of medical necessity decisions. House Bill 820 curtails AI use by payers by requiring that all decisions that could delay, deny or alter patient care be made by a physician. Nonetheless, payers may still use AI to support clinicians as long as certain circumstances are met.

The law also supplements the quarterly reports that health insurers are required to submit to the state, which typically detail various claim payment statistics. Now, insurers will be required to detail the number of adverse claim payment decisions involving AI, algorithms or other software.

Nebraska. Legislative Bill 77 passed on June 6, 2025, and requires that individuals (dubbed utilization review agents under the statute) make decisions to deny, delay or modify a health care claim. [L.B. 77, 109th Neb. Leg., 1st Sess. (2025), <https://legiscan.com/NE/text/LB77/2025>.] Moreover, though utilization review agents may use AI to assist their work, the AI (or other algorithms) used must be disclosed to the department of insurance, the provider and the enrollee, and must be posted publicly on the network's website.

Texas. In a more market-friendly stance, Texas's approach to AI regulation has been focused on transparency (as opposed to outright prohibition). First, Texas passed House Bill 149 on June 22, 2025 (effective Jan. 1, 2026), which is dubbed the Texas Responsible Artificial Intelligence Governance Act, or TRAIGA. [H.B. 149, 89th Tex. Leg., Reg. Sess. (2025), <https://capitol.texas.gov/tlodocs/89R/analysis/html/HB00149S.htm>.]

TRAIGA generally requires broad "clear and conspicuous" disclosures to consumers that they are interacting with artificial intelligence — with more onerous disclosure requirements for its use in health care. TRAIGA also prohibits AI from being designed to manipulate human behavior or engage in unlawful discrimination.

In addition, Texas passed Senate Bill 1188 in 2025, which specifically addresses AI use in the provision of health care services. [S.G. 1188, 89th Leg., R.S. (Tex. 2025), <https://capitol.texas.gov/tlodocs/89R/billtext/html/SB01188F.htm>.] It provides that AI may be used for diagnostic purposes if:

- The practitioner is acting in the scope of their license,
- The use of AI is not otherwise prohibited by law, and
- The practitioner reviews all records created by AI in a manner consistent with medical standards.

Further, the law requires that all records used by an AI system be kept in the United States.

States targeting AI in behavioral health

Following is a recap of three states targeting AI in behavioral health. The states include Illinois, Nevada and Utah.

Illinois. In a more targeted approach, in August 2025, Illinois passed House Bill 1806 in an attempt to specifically curtail AI use in therapy and psychotherapy services. [H.B. 1806, 104th Ill. Gen. Assemb., Reg. Sess. (2025), <https://ilga.gov/documents/legislation/104/HB/PDF/10400HB1806lv.pdf>.]

The Wellness and Oversight for Psychological Resources Act allows providers to use AI for administrative purposes, but it draws the line at any substantive AI use by a provider when rendering care.

The law (as with the states below) is more restrictive than others in California or Arizona, aimed at, for instance, insurance claim decisions, as it does not at all allow AI use for clinical assistance. It is less restrictive, however, than these other states in the sense that it is targeted at a specific industry — behavioral health care services.

Nevada. Similar to the approach in Illinois, Nevada implemented Assembly Bill 406 on July 1, 2025, to curtail the use of AI in behavioral health treatments. [A.B. 206, 83rd Nev. Leg., Reg. Sess. (2025), <https://www.leg.state.nv.us/App/NELIS/REL/83rd2025/Bill/12575/Text>.] Specifically directed at AI chatbots being used in public schools, the law prohibits AI systems from providing (or representing to provide) mental health services. Notwithstanding, school counselors can still use AI for administrative tasks.

Utah. Similar to the states above, restrictions on AI use in mental health under Utah's House Bill 452 are focused on AI chatbots. [H.B. 452, 2025 Gen. Sess. (Utah 2025), <https://legiscan.com/UT/text/HB0452>]

[id/3170911](#) .] It does not prohibit the use of chatbots, but instead requires clear disclosure that a chatbot is not human at the beginning of any interaction. Further, it restricts the use of any data obtained in an interaction.

State Common Law

In addition to state legislatures, there are examples of plaintiffs challenging payer usage of AI based on existing law. Primarily, plaintiffs seek to establish a contractual requirement or representation by the payer that their claims payment decisions were made by real clinicians. The plaintiffs then allege a breach of that contract when a payer allegedly uses AI in claim payment determinations, as the following two cases illustrate.

Estate of Lokken v. UnitedHealth Group: Filed in the Minnesota federal court in February 2023, the plaintiffs allege UnitedHealth used an AI model called nH Predict to override physician recommendations and discontinue coverage for post-acute care for elderly and disabled Medicare Advantage patients. The lawsuit claims the AI model had a high error rate and that employees were disciplined for deviating from its projections.

Though many claims were found to be preempted by the Employee Retirement Income Security Act, the plaintiffs' breach of contract actions premised on representations that claim payment decisions were made by clinical services staff or physicians survived the motion to dismiss. [*Estate of Gene B. Lokken v. UnitedHealth Group, Inc.*, No. 0:23-cv-03514 (D. Minn. Feb. 13, 2025), <https://www.jdsupra.com/legalnews/unitedhealthcare-must-face-state-law-8442700/> .]

Barrows v. Humana: Similar to the *Estate of Lokken* case, this lawsuit alleges Humana also used the nH Predict AI model to deny coverage for medically necessary care. Western District of Kentucky U.S. District Judge Rebecca Grady Jennings' Aug. 14, 2025, ruling built on the *Estate of Lokken* ruling and allowed common law breach of contract claims to proceed. [*Barrows v. Humana, Inc.*, No. 3:23-cv-00654-RGJ, 2025 WL___ (W.D. Ky. Aug. 14, 2025), <https://law.justia.com/cases/federal/district-courts/kentucky/kywdce/3:2023cv00654/132899/82/> .] The judge made the distinction that "the question is not whether the use of AI to make coverage opinions is prohibited under the Medicare Act, but whether insurance companies' use of AI is in violation of their contract with insureds."

Conclusion

AI is here to stay; it is only a matter of where it will sit and how much room it will take. The legislation passed by state governing bodies and the outcomes of ongoing lawsuits may have ripple effects throughout the health care industry and may also be looked to by neighboring regulators designing the next generation of legislation.

Without question, the legal landscape as it relates to the use of AI in health care looked vastly different just a year ago. It will look vastly different a year from now.

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CMS Extends Site-neutrality Payment Reductions

What comes next?

By *Nikesh Jindal and Marcia Foti*

The Centers for Medicare and Medicaid Services published the calendar year 2026 Medicare hospital outpatient prospective payment system final rule in November. As part of that final rule, CMS finalized its proposal to apply the physician fee schedule equivalent payment rate for any codes assigned to the drug administration ambulatory payment classifications when these services are provided at off-campus provider-based departments, or PBDs, excepted from Section 603 of the Bipartisan Budget Act of 2015.

In the final rule, CMS argued these changes are warranted because drug administration services have been increasingly performed at higher-acuity and higher-cost settings of care (i.e., off-campus PBDs) due to the higher payment rates available through the OPPS framework at these PBDs. By lowering those rates for drug administration services to the same rates under the physician fee schedule, CMS seeks, through this site-neutrality policy, to reduce overall expenditures under the OPPS in a way that is not budget neutral.

Furthermore, CMS indicated in the final rule that it may seek to extend site-neutrality payments to other services in future years, which could result in additional significant payment reductions to providers.

This is not the first time CMS has sought to lower payments to off-campus PBDs through site-neutrality policies. In 2019, CMS imposed site neutrality for evaluation and management, or E/M, services performed at off-campus PBDs, which was subject to a legal challenge from providers. [See *American Hospital Association v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020).] Although CMS prevailed in that litigation, the legal landscape has changed in significant and consequential ways that call into question the continued weight of that precedent.

Indeed, as discussed further below, CMS' authority to impose these site-neutral policies may be subject to further judicial scrutiny now that the Supreme Court has repudiated the principles of Chevron deference in its recent holding in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

Background on CMS' Site-neutrality Efforts

In 2019, CMS first proposed controlling what it deemed unnecessary increases in outpatient volume by reducing OPPS payments to the equivalent physician fee schedule rate. [83 Fed. Reg. 37,046, 37,142.] Specifically, CMS cited its authority under Section 1833(t)(2)(F) of the Social Security Act to "develop a method for controlling unnecessary increases in the volume" of services as the basis to cut E/M reimbursement rates at off-campus PBDs to the equivalent physician fee schedule rate.

Additionally, CMS made this rate cut without applying a budget-neutrality adjustment because it took the position that volume-control methods implemented pursuant to Section (t)(2)(F) did not require budget neutrality. [83 Fed. Reg. at 37,142-43.] After receiving many comments that questioned the agency's authority to impose this rate cut, as well as the underlying policy rationale for it, CMS finalized its proposal in the 2019 final rule. [83 Fed. Reg. 58,815, 59,004-15.]

The American Hospital Association and various hospitals subsequently brought a lawsuit challenging the site-neutrality changes contained in the 2019 final rule. Although the providers initially prevailed at the district court, the D.C. Circuit on appeal reversed and ruled in favor of CMS in upholding the regulations.

Notably, fundamental to its decision, the D.C. Circuit found that CMS' regulations were entitled to Chevron deference, under which the courts defer to the agency's reasonable interpretation of an ambiguous statute. [Am. Hosp. Ass'n, 964 F.3d at 1239.] Because the statute did "not unambiguously foreclose [the Department of Health and Human Services'] adoption of a service-specific, non-budget-neutral rate cut as a 'method for controlling unnecessary increases in' volume," the D.C. Circuit asked only whether the agency's interpretation was "based on a permissible construction of the statute." [*Id.* at 1244.] Under this highly deferential standard, the D.C. Circuit found HHS had the requisite authority to implement the challenged site-neutrality policy. [*Id.* at 1245.]

The 2026 Final Rule

In the 2026 final rule, CMS cited the same statutory authority to apply the equivalent physician fee schedule payment rate for any codes assigned to the drug administration ambulatory payment classifications when provided at an excepted off-campus PBD. CMS argued that such a change was necessary because there has been an increased volume in drug administration services, such as chemotherapy treatment, being administered in off-campus PBDs. [90 Fed. Reg. 53,448, 53,804-06.]

This regulatory change is consequential, especially as CMS is again not implementing the site-neutrality adjustment in a budget-neutral manner. As a result, CMS estimates the proposed impact to hospital providers will be \$290 million in 2026. [90 Fed. Reg. at 53,808.]

CMS has further signaled that it is interested in expanding site neutrality to other services through future rulemakings, which could result in additional significant payment reductions to providers. In the 2026 proposed rule, CMS issued a request for information for other areas in which it should apply site neutrality. [90 Fed. Reg. 33,476, 33,690-91.] And, in the 2026 final rule, CMS stated it would continue to explore these areas in future years. [90 Fed. Reg. at 53,821.]

The Effect of *Loper Bright*

Following the D.C. Circuit's decision in *American Hospital Association v. Azar*, the Supreme Court repudiated the underpinnings of Chevron deference in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). In *Loper Bright*, the Supreme Court instructed judges to determine and apply the best reading of the statutory provisions at issue in assessing whether an agency has acted within its statutory authority, rather than afford any special deference or weight to the government's proffered reading. [*Id.* at 412-13.]

The Supreme Court's decision in *Loper Bright* — overruling Chevron and making clear that CMS is not entitled to any such deference — removes this foundational basis of the D.C. Circuit's opinion in *American Hospital Association v. Azar* and reopens the question of whether CMS has the authority to impose rate reductions for drug administration ambulatory payment classifications and other services performed at excepted off-campus PBDs.

Commenters, in response to the recent rule, raised these concerns about CMS' authority to extend an overarching regime of site neutrality. For example, under Section 603 of the Bipartisan Budget Act of 2015, Congress prescribed that Medicare would pay the same rates for medical services regardless of where the services are provided. However, Congress specifically excepted all off-campus PBDs that were providing services before the enactment of Section 603, grandfathering in the higher hospital rates. Commenters made the point that Congress's command was clear and unequivocal that excepted off-campus PBDs were exempt from payment changes such as the site-neutrality policy contained in the 2026 final rule.

Similarly, commenters argued that Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" do not authorize CMS to deviate from Congress's command that the HHS secretary pay for medically necessary services at statutorily prescribed rates. Commenters also noted that merely because the Medicare statute sets forth different payment rates for the same services depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary." These commenters reasoned that CMS' proposed reliance on Section (t)(2)(F) to set aside those payment rates and pay the least costly alternative exceeds its statutory authority.

Commenters also argued that CMS' reading would render superfluous the authority actually delegated to CMS under Section (t)(9)(C) to make appropriate adjustments to the conversion factor where CMS, under Section (t)(2)(F), has determined there has been an unnecessary increase in volume of services. Even assuming that Section (t)(2)(F) allows for site-neutral cuts, they argued that any such cut must be done in a budget-neutral manner.

Finally, several commenters noted that CMS' expansive view of its rate-setting authority under Section (t)(2)(F) runs afoul of the major questions doctrine, which bars agencies from making regulatory pronouncements of "vast economic and political significance" without clear statutory authorization. [*West Virginia v. Environmental Protection Agency*, 597 U.S. 697, 716 (2022).] Specifically, these commenters questioned why Congress would have provided such specific requirements for setting OPPS rates but then allowed essentially unbound authority to CMS to recalibrate and modify the rates as it chooses under Section (t)(2)(F).

None of these concerns swayed CMS as it finalized the site-neutrality change for drug administration ambulatory payment classifications in the 2026 final rule, as originally proposed.

Conclusion

Recent changes in administrative law, including the end of Chevron deference and the clear establishment of the major questions doctrine as a canon of statutory interpretation, have created significant questions about the continued authority of CMS to adopt site-neutrality payment rate cuts. Given the potential significant financial impact to providers, especially as CMS signals its intent to continue expanding site neutrality in the future, it would come as no surprise if providers seek to challenge CMS' regulatory approach and litigate the nature and extent of the agency's authority in this area.

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The Rural Health Transformation Program

Where it is and where it is going

By *Dan Berkowitz and Scott Dziengelski*

The One Big Beautiful Bill Act, or OBBBA, established the Rural Health Transformation Program, a \$50 billion fund for states to use over a five-year period to improve rural health care access and quality. [Pub. L. No. 119-21(2025).]

The RHT program was created as a response to concerns that OBBBA could have adverse impacts on providers and patients in rural communities. All 50 states met a November 2025 application deadline for submitting a plan to the Centers for Medicare and Medicaid Services for how they would use their share of RHT program funding. On Dec. 29, the amounts awarded to each state were announced by CMS.

Given the amount of money and the flexibility of how it can be spent, the RHT program has the potential to transform entire health care sectors within a state. For example, the RHT program may substantially increase the number of behavioral health providers in a state who have electronic health records and can achieve interoperability with the rest of the health care system. For providers and health systems seeking to leverage these funds, they should review their state's CMS application and consider advocacy to secure funds or to seek amendments to the application.

OBBA Background

In the Congressional budget process, each chamber (House and Senate) adopts a budget resolution establishing budgetary goals for the year. When these budget goals conflict with existing laws on federal revenue and spending, those laws need to be revised to fit the budget goals or reconciled with the budget.

Congress can pass legislation to achieve this reconciliation, known as the budget reconciliation process. A codicil of this parliamentary procedure is that Senate debate on budget reconciliation legislation is limited. Without that codicil, it would require a three-fifths majority vote, or 60 votes, to end debate on the bill.

Because reconciliation limits debate, a bill cannot be filibustered and can pass with only 50 votes, bypassing the Senate cloture rule. This lower Senate threshold has made budget reconciliation a popular means for passing large, partisan legislation. The Republican House, Senate and president used the budget reconciliation process to pass OBBBA.

OBBA included numerous provisions related to taxation, energy, the environment and health care. Within the health care changes were reforms to the Medicaid program. Some of those Medicaid changes raised concerns

about impacts on patients and providers, particularly those in rural communities. As a means of addressing those concerns, the RHT program was included in OBBBA before it was signed into law on July 4, 2025.

Structure of the RHT Program

The RHT program was created in Section 71401 of OBBBA, providing \$10 billion per year for five years (fiscal 2026-2030) to states to improve access to and the quality of health care in rural communities. In the context of a U.S. health care system that spends roughly \$4.6 trillion a year, the \$10 billion in annual RHT program funding may seem small. [Congress, Section on CRS Products (Library of Congress), *U.S. Health Care Coverage and Spending* (2025), <https://www.congress.gov/crs-product/IF10830>.] In the context of what the federal government spends on rural health care, however, it is significant.

By comparison, the four major federal programs supporting rural health care facilities — the critical access hospital program (\$4 million each to 1,369 facilities in 2022), the Medicare-dependent hospital program (\$125 million annually to 140 facilities), the sole community hospital program (\$835 million combined to 467 hospitals in 2022) and the Medicare low-volume hospital adjustment (\$400 million annually to 450 facilities) — together account for approximately 13.7% of the total funding that the RHT program will distribute. [White House, Section on Uploads, *Memorandum Re: The One Big Beautiful Bill is a Historic Investment in Rural Healthcare* (2025), <https://www.whitehouse.gov/wp-content/uploads/2025/07/OBBB-Rural-Memo.1.pdf>.] Additionally, unlike programs such as Medicaid, states are not required to provide matching funds for RHT program funds.

To receive RHT funding, states were required to submit, by Nov. 5, 2025, a one-time application to CMS that included, among other components, a rural health transformation plan that details how the state intends to use its portion of program funds. CMS approved those applications by the close of 2025. States can amend their plans or file new applications in future years, as their needs change.

Annual RHT program funding, \$10 billion per year for five years, will vary by state. Variations will be based on the two ways CMS will distribute the funds:

- First, half of the funding will be distributed to states as baseline funding. The amount is distributed equally to each state with an approved application. Each state will receive \$100 million annually (\$5 billion total across all states) for the five years of the program.
- Second, half of the funding will be distributed to states as workload funding. The remaining \$5 billion each year will be allocated to states on an unequal basis. The amount each state receives will be “based on the content and quality of state application and rural factors” in their rural health transformation plan, as determined by CMS.

Factors CMS will consider in determining workload funding distributions to states will fall into two categories: rural facility and population score factors, and technical score factors.

Rural facility and population score factors are demographic and statistical factors about a state itself, such as the absolute size of the rural population and the proportion of rural health facilities.

Technical score factors are specific to how a state intends to spend its allocation of RHT program funding. To understand this factor, CMS will review a state’s rural health transformation plan submitted with its application. [42 U.S.C. 1397ee(h)(2)(A)(i).] The appendix in CMS’ notice of funding opportunity for the RHT program includes a detailed explanation of each factor it will consider in the technical score. [Centers for Medicare and Medicaid Services, Section on Rural Health Transformation Program (2025), <https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview>.]

RHT program funds awarded to states are flexible but do have limitations. For example, under OBBBA, a state must use the funds in at least three ways described in the law. These uses include prevention and chronic disease; provider payments; consumer technology solutions; training and technical assistance; workforce; information technology (IT) advances; appropriate care availability; behavioral health; and innovative care. Each use is described in detail in the notice of funding opportunity.

Within the categories of approved spending, there are unallowable costs. Unallowable costs that have drawn the most attention include funds that cannot be used for “new construction,” “to replace payment for clinical services that could be reimbursed by insurance,” and “no more than 5% of total funding … can support funding the replacement of an [electronic medical record] system if a previous [Health Information Technology for Economic and Clinical Health Act, or HITECH] certified EMR system … is in place as of September 1, 2025.”

Status of the RHT Program

CMS reported that all 50 states submitted RHT program applications by the November deadline, and that the agency would review each application to ensure all application requirements were met. CMS announced Dec. 29 that all 50 states will receive RHT program awards. The amounts for each state vary, ranging from \$147 million to \$281 million. The 2026 program funding will be available in the first quarter of 2026.

Review of State RHT Program Applications

Thirty states released their RHT program applications to the public; 20 states provided a summary of their applications. The applications vary widely, although there are a few clear trends. On average, states plan to use RHT program funding for four to seven different initiatives, with most costing more than \$1 billion per state for five years. Within those initiatives, areas of common focus include addressing workforce shortages, increasing emergency medical services, and leveraging federally qualified health centers to better address chronic disease and maternal health.

Two additional trends in the applications demonstrate the potential for the RHT program to be transformative within a state or health care sector: technology modernization and support for behavioral health care. Multiple state applications include adopting or upgrading electronic health record, or EHR, systems or health information technology, and expanding access to mental health and substance use disorder treatment. Together, these trends could be transformative as EHRs are the only new technology that can be applied at scale in behavioral health care. Additionally, behavioral health care providers have historically lagged in EHR adoption.

It is not surprising that states have focused on these two areas. Expanding EHR capacity and achieving interoperability at behavioral health care facilities is particularly beneficial to rural communities. It reduces emergency department boarding, creates faster discharge from inpatient to the community, strengthens care continuity, helps integrate behavioral health care providers into health information exchanges and prescription drug monitoring programs, and improves cybersecurity. This also meets two criteria the law requires be met to receive CMS approval. Specifically, it meets two key criteria cited in the notice of funding opportunity for how funds can be used: IT advances and behavioral health.

The IT advances criterion states that funds can be used to provide “technical assistance, software, and hardware for significant information technology advances designed to improve efficiency, enhance cybersecurity capability development, and improve patient health outcomes.” Research overwhelmingly supports the finding that EHRs result in improved efficiency and improved patient health outcomes. [Aykut Uslu and Jürgen Stausberg, *Value of the Electronic Medical Record for Hospital Care: Update From the Literature*, 23(12) J. Med. Internet Res. no. 12 e26323 (2021), <https://www.jmir.org/2021/12/e26323>.]

The behavioral health criterion states that funds can be used to support “access to opioid use disorder treatment services [and] other substance use disorder treatment services, and mental health services.” By funding the adoption of EHRs and advancing EHR interoperability among psychiatric hospitals, adult residential behavioral health care facilities, youth residential behavioral health care facilities and opioid treatment, this criterion is met.

Meeting the IT advances and behavioral health criteria, a state would only need to meet one more criterion to satisfy the law’s requirement that RHTP funding be applied to three criteria identified in the law. Additionally, this will increase the overall funding a state receives through the RHT program.

The notice of funding opportunity appendix section on point scoring details describes technical score “F. 2. Data infrastructure” and details how a state can score points on its application to increase its share of RHT program funding by agreeing to use the funding for high-quality data infrastructure and facilitating interoperability. To help states understand what is meant by high-quality data infrastructure and facilitating interoperability, the notice of funding opportunity links to documents describing the importance of EHRs. This shows CMS’ clear intent to encourage states to use RHT program funding for EHR adoption — by rewarding them for doing so.

As noted, the notice of funding opportunity states that no more than 5% of a state’s RHT program funding can be used to replace an EHR system if a previous HITECH-certified system is in place. Because behavioral health care providers were excluded from the HITECH Act, this limitation does not apply to them. This makes clear CMS’ intent to have psychiatric hospitals, adult residential behavioral health care facilities, youth residential behavioral health care facilities and opioid treatment programs use RHT program funds to adopt EHRs.

EHRs and Interoperability Among Behavioral Health Care Providers

The HITECH Act, which included \$36.5 billion to create a nationwide network of EHRs, was signed into law in 2009. Of the \$36.5 billion, \$19 billion was committed to advance EHR use through monetary incentives. Behavioral health care providers were explicitly excluded from accessing these funds. There were several reasons, but the greatest was that Congress had limited funds available for the HITECH Act; to control costs, Congress excluded behavioral health care providers.

This cost-based decision to exclude behavioral health care providers was summed up by former Rep. Pete Stark (D-Calif.), a driving force behind the HITECH Act, when he said:

[S]ome have faulted HITECH for not making incentive payments available to ... mental health professionals, facilities ... and other providers who do not currently qualify. Spending on health IT in the stimulus bill was limited. ... Congress decided to focus first on ... hospitals, because they are where the largest share of healthcare dollars are spent. Furthermore, providing sizable incentive payments to a limited number of providers has a greater impact than spreading payments more thinly to a larger number of providers.

The impact of the HITECH Act on EHR adoption was significant. EHR utilization is nearly 100% for general acute care hospitals. In contrast, according to the Medicaid and CHIP Payment and Access Commission, or MACPAC, 6% of behavioral health care facilities use EHRs and 29% of substance use disorder treatment centers use EHRs. [Medicaid and CHIP Payment and Access Commission, *June 2022 Report to Congress of Medicaid and CHIP*, ch. 4, Encouraging Health Information Technology Adoption in Behavioral Health: Recommendations for Action, <https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-4-Encouraging-Health-Information-Technology-Adoption-in-Behavioral-Health.pdf>.] The MACPAC report attributes this low adoption to a lack of federal incentives.

An absence of technology in behavioral health impacts providers and patients. EHRs provide multiple benefits, including improving patient safety, reducing medical errors and increasing efficiency in health care delivery. A systematic review of 23 independent studies found EHRs in every case “demonstrate a positive effect on the quality of health care.” [Uslu and Stausberg, *Value of the Electronic Medical Record* e26323, <https://www.jmir.org/2021/12/e26323>.]

A study of EHR use in Vermont found a 60% decrease in near-miss medication events; a 20% increase in completion of daily fall assessment, helping to avoid prolonged hospital stays; and a 25% drop in the number of patient charts needing to be pulled for signing orders and dictated reports. [B. Bell and K. Thornton, *From Promise to Reality: Achieving the Value of an EHR*, 65 Healthc. Fin. Mgmt. 51 (2011).] EHR-based interventions have also been associated with a reduction in 30-day and 90-day hospital readmissions. [B.S.B. Pattar et al.,

Electronic Health Record Interventions to Reduce Risk of Hospital Readmissions: A Systematic Review and Meta-Analysis, 8 JAMA Netw. Open e2521785 (2025), <https://doi.org/10.1001/jamanetworkopen.2025.21785> .

CMS has previously noted the importance of EHR adoption. The agency points to EHRs improving patient care by reducing medical errors, improving the accuracy and clarity of medical records, making health information more available, reducing duplicate tests, reducing treatment delays, allowing patients to make better informed decisions, and reducing medical errors by improving the accuracy and clarity of medical records. [Centers for Medicare and Medicaid Services, Section on Initiatives, *Electronic Health Records*, <https://www.cms.gov/priorities/key-initiatives/e-health/records>.] Without EHRs, behavioral health care providers and their patients miss out on these benefits, often relying on paper medical charts, filing cabinets and fax machines. This paper-based system makes it difficult for clinicians to deliver high-quality care.

The workflow challenges of a paper-based system also pose significant recruiting and workforce retention challenges for behavioral health care facilities. A lack of EHRs has two direct impacts on the workforce:

- Facilities must hire more staff due to the inefficiency of a paper-based system.
- Physicians and nurses are less likely to work at a facility without an EHR system, making it more difficult to recruit and retain staff in challenging fields, such as behavioral health, or in rural areas.

Most importantly, the absence of EHR systems in behavioral health care has its greatest impact on patients. EHRs support value-based care by providing clinicians and population health leaders with access to comprehensive patient data, including patient histories, test results, care plans and, ultimately, outcomes. This information directly impacts the quality of care patients receive.

Lack of EHRs is a long-standing issue in behavioral health care. Since 2010, more than six bills intended to remedy this issue have been introduced in Congress. However, none of those bills passed. As a result, virtually no federal funding for EHR adoption and interoperability has reached behavioral health care. If the RHT program can increase EHR adoption and interoperability among behavioral health care providers, it could be transformative for the industry and for patients.

Future of the RHT Program

Although states need to apply only once, they may amend their rural health transformation plans and apply again. This will likely occur as the nature of the RHT program becomes clearer during implementation or as new issues arise for states. There is also the potential for changes in priorities within CMS. The five-year RHT program will continue into the next presidential administration. A new administration may mean new priorities for CMS, including new priorities for the RHT program.

There remains an opportunity to secure funding from the RHT program. Interested parties should review their state's application to identify what funding may apply to their work. If none of the provisions in the application apply, advocates could push for a state to amend its 2025 application and reapply in a subsequent year.

Conclusion

OBBA's RHT program has the potential to reshape how states provide health care to rural communities across the country. With all 50 states engaged and funding amounts allotted, a clearer picture is emerging of what can and will be accomplished with \$50 billion over five years.

Among the important takeaways from the program so far is that historically overlooked or underfunded health care sectors could receive significant funding support. Many state applications focus on increasing behavioral health care providers' use of EHRs and increasing the number who can achieve interoperability with the rest of the health care system. Providers and health systems seeking to leverage these funds should review their state's application to CMS and consider advocacy to secure funding or seek amendments to the application.

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Aetna's New 'Level of Severity Inpatient Payment Policy' and the Two-midnight Rule

Policy raises questions as it appears to override federal law and may violate state contract laws

By Dana Berkowitz and Jennifer Simmen Lewin

Commercial health plans typically require contracting health care providers to comply with the health plans' policies. Such policies may include procedures and timelines for seeking prior authorization, submitting medical bills, and appealing denials or underpayments.

Some plans, however, take their policies further. What happens when a plan policy purports to override federal law? What if the policy changes the basic reimbursement terms of the contract?

A recent policy announced by Aetna — slated to take effect Jan. 1, 2026 — raises these questions in the context of inpatient reimbursement for Medicare Advantage members.

Two-midnight Rule Defines Inpatient Care, Applies to Medicare Advantage Plans

More than half of all Medicare beneficiaries participate in Medicare Advantage plans. Under federal regulations, Medicare Advantage plans must pay for all services that are covered by Medicare Part A, or original Medicare.

[\[42 U.S.C. § 1395w-22\(a\)\(1\)\(A\)\]](#) ("[E]ach [Medicare Advantage plan] shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI of this chapter, *those items and services ... for which benefits are available under parts A and B of this subchapter to individuals residing in the areas served by the plan.*"") (emphasis added); [42 C.F.R. §422.101](#) ("[E]ach [Medicare Advantage plan] must meet the following requirements: (a) *Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare ...*"") (emphasis added).]

Medicare Advantage plans must also comply with coverage guidelines issued by the Centers for Medicare and Medicaid Services for original Medicare. [\[42 C.F.R. §422.101\]](#) ("[E]ach [Medicare Advantage plan] must meet the following requirements: ... (b) Comply with — ... (2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in this part."].

CMS has defined what constitutes an inpatient admission for the purposes of coverage and payment under Medicare Part A and, thus, for Medicare Advantage plans as well. Since 2013, that definition has included the two-midnight rule, which provides:

Except as specified in paragraphs d(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights. [42 C.F.R. § 412.3(d)(1).] The factors that led the physician to expect hospital care that crosses two midnights must be documented in the medical record. [42 C.F.R. § 412.3(d)(1)(ii) ("The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.").]

The two-midnight rule does not distinguish between inpatient and outpatient levels of care. If the admitting physician expects the patient to need hospital care that crosses two midnights, the inpatient standard is met. The two-midnight rule is a bright-line test that CMS adopted with the stated goal to reduce uncertainty and variation in reimbursement for inpatient admissions. [78 Fed. Reg. 17,486, 27,648 (May 10, 2013) (purpose to "reduce uncertainty regarding the requirements for payments to hospitals ... under Medicare Part A related to when a Medicare beneficiary should be admitted as a hospital inpatient, in this final rule").]

CMS has made clear that the two-midnight rule applies to Medicare Advantage plans. [See, e.g., Centers for Medicare and Medicaid Services, *The 2 Midnight Rule & Medicare Advantage (MA) Plans: Frequently Asked Questions* (June 13, 2024), ("As consistent with current MA policy, MA plans have the flexibility to enter into contract arrangements with hospitals to provide Medicare benefits in addition to those provided under Original Medicare. Therefore, an MA plan may choose to cover inpatient hospital stays that are **shorter** than those anticipated by the order and certification requirements. In any event, MA plans must ensure they are providing all Medicare Part A and B benefits without additional restrictions and that the plan's policy for inpatient stays is clear to enrollees.").]

In 2023, CMS expressly "reiterated," "clarified," and "affirmed" its "existing" and "longstanding policy" that Medicare Advantage plans must comply with the two-midnight rule. [88 Fed. Reg. 22,120, 22,190 (April 12, 2023) (explaining that proposed regulatory changes are consistent with "a longstanding policy in MA based on how section 1852 of the [Social Security] Act requires MA Plans to cover items and services for which benefits are available under original Medicare" and proposing "to codify these existing standards for medical necessity decision-making"); *id.* at 22,191 ("We received several comments thanking CMS for reiterating that MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws ... and for clarifying that this includes coverage criteria for inpatient admissions at [42 CFR 412.3](#) ... " – i.e., the two-midnight rule."); *id.* ("We affirm here that the criteria listed at those regulations are applicable in MA.").]

Despite this guidance from CMS, providers have expressed concerns that some Medicare Advantage plans still do not apply the two-midnight rule to evaluate the medical necessity of inpatient hospital admissions, and that the plans instead apply more stringent criteria, such as InterQual® or MCG Health care guidelines.

Aetna's Policy to Reimburse at Observation Rates Care that Satisfies Two-midnight Rule

On Aug. 1, 2025, Aetna published a provider newsletter that announced a new "level of severity inpatient payment policy." [Aetna, OfficeLink Updates (August 2025), 90-day notices: *level of severity inpatient payment policy*, <https://www.aetna.com/content/dam/aetna/pdfs/olu/officelink-updates-august-2025-olu.pdf>.] Aetna described its purported policy as a "new payment structure for Medicare inpatient claims." [Id.] The key language reads as follows:

Effective November 15, 2025, we'll adopt a new reimbursement approach for hospital stays of 1+ midnight in cases where a member is urgently or emergently admitted to a hospital and the provider has submitted an inpatient order.

- We'll approve the inpatient stay without a medical necessity review **and pay the claim at a lower level of severity rate that's comparable to your rate for observation services.****
- If the inpatient stay meets MCG (Aetna Supplemental Guidelines for inpatient admissions), we'll pay the claim at your inpatient rate in accordance with the hospital agreement. [*Id.* (emphasis added).]

In short, Aetna announced that it would reimburse contracted providers at their observation rate instead of their inpatient rate for overnight hospital care of any duration following an urgent inpatient admission — unless the provider proves that the care meets MCG care guidelines. The new approach thus creates a two-tiered rate structure for inpatient care that meets MCG care guidelines (payable at the contracted inpatient rate) and inpatient care that does not meet MCG care guidelines (payable at the lower observation rate).

Aetna asserted in its announcement that this new approach would not involve using MCG care guidelines “to determine whether the inpatient stay is medically necessary,” but rather only “to determine the severity of an inpatient stay and whether that severity justifies the inpatient contract rate.” [*Id.*] By characterizing the change as one to provider payment rather than medical necessity, Aetna likely sought to sidestep the two-midnight rule, which defines the medical necessity of inpatient care for Medicare Advantage members. Aetna will not use the word “observation” to describe care that meets the two-midnight rule but not MCG care guidelines; it will simply pay for such care at the observation rate.

Aetna described the new approach as a positive development for providers because it will help them get paid faster. Instead of denying inpatient stays that do not meet MCG care guidelines (as Aetna does now), Aetna will pay at the observation rate without requiring the provider to rebill. [*Id.*]

Providers Push Back, and Aetna Updates Policy and Delays Implementation

On Sept. 15, 2025, the American Hospital Association published a letter urging Aetna to rescind the policy announcement. [American Hospital Association, Section on Advocacy, Letter/Comment, *AHA Urges Aetna to Rescind Level of Severity Inpatient Payment Policy*, <https://www.aha.org/lettercomment/2025-09-15-aha-urges-aetna-rescind-level-severity-inpatient-payment-policy>.] The AHA observed that Aetna's new approach “appears to circumvent established regulatory standards regarding coverage for Medicare Advantage beneficiaries” — i.e., the two-midnight rule. [*Id.*] The AHA argued that although Aetna characterized its reliance on MCG care guidelines “solely as an issue of payment” and not one of medical necessity, CMS had adopted coverage guidelines precisely “to safeguard beneficiaries against inappropriate denials and downgrades of care.” [*Id.*]

The AHA also warned of other negative consequences of the newly announced policy, including that it could “distort data that have a direct bearing on Aetna's performance” under the Medicare Advantage star ratings program and that it would “further stress an already unstable health care system at a time when hospital costs for caring for patients continue to rise.” [*Id.*]

Aetna's new approach was set to take effect on Nov. 15, 2025. On Nov. 6, Aetna issued a provider newsletter containing “additional detail and clarity to support a smooth transition for the Level of Severity Inpatient Payment Policy.” [Aetna, OfficeLink Updates (November 2025), *Policy changes: level of severity inpatient payment policy update*, <https://www.aetna.com/content/dam/aetna/pdfs/olu/officelink-updates-november-2025-olu-edition-11-6.pdf>.] The November newsletter postponed the effective date of the change to Jan. 1, 2026. It also modified the prior announcement, which applied to “hospital stays of 1+ midnights,” by limiting it to “urgent/emergent inpatient stays of at least 1 midnight but less than 5 midnights.”

The AHA expressed appreciation for Aetna's decision to delay implementation, which "provides additional time for hospitals and health systems to prepare and for continued dialogue on the policy's impact." [American Hospital Association, Section on News, Headline, *Aetna delays, issues additional details on 'level of severity inpatient payment' policy*, <http://aha.org/news/headline/2025-11-14-aetna-delays-issues-additional-details-level-severity-inpatient-payment-policy>.]

Conclusion

As of this publication, it remains to be seen whether Aetna will follow through on its new (modified) approach, or whether objections from the provider community or regulators will cause Aetna to reconsider or make further modifications.

Notably, many providers contract for the right to object to new payer policies that may cause a material financial impact. Providers who have negotiated a higher reimbursement rate for inpatient care than for observation care may experience a negative financial impact from the switch to a two-tiered rate structure for inpatient stays.

Moreover, Aetna's assertion that its new policy changes payment terms could implicate common contractual provisions and state law that forbids unilateral contract amendments. There is little public information to indicate whether providers have asserted such objections to Aetna.

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Texas District Court Vacates CMS Medicaid Financing Rule

Key takeaways for providers

By Dennis Mkrtchian

The U.S. District Court for the Eastern District of Texas issued a significant opinion Sept. 24, 2025, involving Medicaid financing mechanisms used to support Medicaid supplemental payments. [*Texas v. Centers for Medicare & Medicaid Servs.*, No. 6:23-CV-161-JDK, 2025 WL 2724375 (E.D. Tex. Sept. 24, 2025).]

The court set aside portions of the Centers for Medicare and Medicaid Services' 2024 final rule and two related informational bulletins issued in 2023 and 2024 concerning Medicaid financing and the federal prohibition on hold harmless arrangements involving provider taxes and state-directed payments. It also permanently enjoined CMS from enforcing that interpretation going forward.

The court's decision is not limited to Texas and, therefore, has practical effects for states and providers nationwide that rely on provider taxes and supplemental financing mechanisms. CMS filed a notice of appeal on Nov. 21, 2025, but the district court's decision remains in place unless and until it is modified on appeal.

For now, the ruling should meaningfully limit CMS' authority to regulate private financial arrangements among providers and clarifies how states may structure the nonfederal share of Medicaid expenditures. This article briefly reviews the statutory and factual background, describes what CMS did in the 2024 final rule and the 2023 and 2024 bulletins, summarizes the court's reasoning, and then turns to practical implications for providers and states.

Background: Medicaid Financing, Provider Taxes, and the Texas and Florida Litigation

Medicaid is funded jointly by the federal government and the states. States may use taxes on health care providers to finance their share of Medicaid costs, provided the taxes satisfy certain statutory conditions. One of those conditions is that the tax may not include a hold-harmless component.

The hold-harmless limitation was enacted after CMS and Congress became concerned that some states were using provider taxes and related payment arrangements to increase federal matching funds without increasing the states' own net contribution. The court highlighted an example where states would impose taxes on hospitals, while simultaneously agreeing to repay hospitals the amount of their tax payment. To address this, Congress enacted the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, which are codified at [42 U.S.C. § 1396b\(w\)](#).

Under that statute, a hold-harmless provision exists if, among other things, the "State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax." [[42 U.S.C. § 1396b\(w\)\(4\)\(C\)\(i\)](#).] The statute directs the federal government to reduce matchable state funds when there is a hold-harmless provision with respect to a provider tax.

In Texas, one of the ways the state finances Medicaid payments is through provider taxes administered at the local level. The state authorizes local governmental entities to impose mandatory payments on hospitals, deposit the revenue into local provider participation funds, and use those funds to support the nonfederal share of Medicaid supplemental payment programs. Consistent with federal law, Texas law prohibits these programs from holding providers harmless.

In 2023, CMS issued an informational bulletin expressing concern about situations in which providers allegedly redistributed Medicaid payments among themselves after receiving them. CMS viewed these private redistribution arrangements as effectively returning tax costs to providers and announced that it would treat them as prohibited hold-harmless arrangements.

The 2023 bulletin also directed states to collect information about such arrangements, make clear to providers that they were not permissible, and condition provider participation in Medicaid on the disclosure of this information. CMS warned that failure to comply could result in deferral or disallowance of federal financial participation.

Texas challenged that 2023 bulletin, and the district court issued a preliminary injunction. [*Texas v. Brooks-LaSure*, 680 F. Supp. 3d 791, 809 (E.D. Tex. 2023).] In that earlier decision, the court explained that the hold-harmless provision in the Social Security Act focuses on guarantees provided by the state or another governmental entity, and that CMS could not extend the statute to private conduct or agreements among providers. That preliminary injunction set the stage for the dispute over CMS' 2024 final Rule. King & Spalding analyzed that earlier decision in the August 2023 publication of *Reimbursement Advisor*.

On March 6, 2024, a Florida district court reached a contrary conclusion by denying Florida's motion for preliminary injunction and granted CMS' motion to dismiss based on the same 2023 bulletin at issue in the Texas case. [*Fla. v. Brooks-Lasure*, No. 23-CV-61595, 2024 WL 965661, at *1 (S.D. Fla. Jan. 29, 2024), *report and recommendation approved*, No. 23-CV-61595-WPD, 2024 WL 962433 (S.D. Fla. Mar. 6, 2024), *aff'd in part, rev'd in part and remanded sub nom. Fla. Agency for Health Care Admin. v. Adm'r for Centers for Medicare & Medicaid Servs.*, No. 24-10875, 2025 WL 3496406 (11th Cir. Dec. 5, 2025).] The court concluded that the bulletin did not constitute final agency action, denied injunctive relief and dismissed the case for lack of jurisdiction. [*Id.*] King & Spalding also analyzed this decision in the April 2024 publication of *Reimbursement Advisor*.

On December 5, 2025, the Eleventh Circuit partially reversed and remanded, holding that the district court erred in concluding that it lacked jurisdiction because the 2023 bulletin did constitute final agency action, while nonetheless affirming the denial of preliminary injunctive relief on the ground that Florida failed to demonstrate a substantial likelihood of success on the merits. [*Fla. Agency for Health Care Admin. v. Adm'r for Centers for Medicare & Medicaid Servs.*, No. 24-10875, 2025 WL 3496406 (11th Cir. Dec. 5, 2025).] Thus, the Florida courts

reached a different conclusion than the Texas district court despite addressing the same informational bulletin and remanded the case for further proceedings.

CMS' 2024 Final Rule and the 2023 and 2024 Bulletins

While the Texas and Florida litigation was ongoing, CMS proceeded with formal rulemaking. In May 2024, the agency issued a final rule revising [42 C.F.R. § 438.6\(c\)\(2\)\(ii\)](#), which sets standards for state-directed payments in Medicaid managed care. Specifically, the final rule added [42 C.F.R §§ 438.6\(c\)\(2\)\(ii\)\(G\)](#) and [438.6\(c\)\(2\)\(ii\)\(H\)](#), which requires states to ensure that these payments complied with federal requirements for financing the nonfederal share, including those involving provider taxes. It also required states to obtain attestations from providers receiving state-directed payments that they were not participating in hold-harmless arrangements as specified in [42 C.F.R. § 433.68\(f\)\(3\)](#).

In the preamble to the rule, CMS explained that it was adopting the view expressed in its 2023 bulletin. It stated that hold-harmless arrangements included situations in which private agreements created a reasonable expectation that providers would receive back all or part of their tax costs, including contractual payment arrangements directing how Medicaid managed care plans pay providers.

The final rule also amended [42 C.F.R. § 430.3](#), which describes different types of disputes that arise under Medicaid and how they are reviewed. A new subsection directed that disputes concerning CMS' approval or disapproval of state-directed payments be heard by the Department of Health and Human Services Departmental Appeals Board rather than by federal courts.

In early 2024, CMS issued another bulletin, adopting the same interpretation of hold harmless arrangements set out in the 2023 bulletin and explaining that it would evaluate financing concerns during the review of preprints for state-directed payments. The 2024 bulletin explained that CMS would evaluate the source of the nonfederal share for state-directed payments during the preprint review process and that states would be required to ensure that providers receiving state-directed payments attest they do not participate in hold-harmless arrangements as described in the regulation.

Texas then amended its complaint to challenge the 2024 final rule and the 2024 bulletin, arguing that they suffered from the same statutory defects as the 2023 bulletin and also raised additional Administrative Procedure Act and constitutional concerns. Both Texas and CMS moved for summary judgment.

The Court's Decision

The district court granted Texas's motion for summary judgment on several counts and enjoined CMS from enforcing its interpretation of the hold-harmless statute. The court vacated the challenged portions of the final rule — [42 C.F.R § 438.6\(c\)\(2\)\(ii\)\(G\)](#) and [42 C.F.R § 438.6\(c\)\(2\)\(ii\)\(H\)](#) — and both bulletins. The court also granted CMS' cross-motion on two counts that Texas had effectively abandoned. The following sections highlight the court's key holdings.

CMS Exceeded Its Statutory Authority

The court held that CMS had expanded the definition of a hold-harmless arrangement beyond what Congress authorized. Under [42 U.S.C. § 1396b\(w\)\(4\)\(C\)\(i\)](#), the court explained that a hold-harmless provision exists when "the State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax."

The court reasoned that the statutory language focuses on circumstances where the state imposes a tax and then provides a payment or offset that guarantees the taxpayer will be held harmless for some or all of the tax cost. In other words, there is a "tight grammatical link" between the government, as the actor providing for the payment, and the guarantee of being held harmless. Thus, the court emphasized that the guarantee must come from the state or another governmental entity.

CMS' interpretation, by contrast, treated private agreements among hospitals or payment arrangements between managed care plans and providers as if they were state-provided guarantees. The court found that this departed from the statutory text, which centers on state action. It explained that CMS' approach effectively conditioned federal matching funds on private financial conduct that states might not know about or control. The court also noted that the Departmental Appeals Board had previously taken the position that a hold-harmless arrangement requires some explicit or direct assurance from the state. The court viewed that prior interpretation as consistent with the statute and inconsistent with CMS' current position.

Texas also challenged the new regulation at § 430.3(e), which directed state-directed payment disputes to the Departmental Appeals Board. The court similarly held that CMS exceeded its authority by directing that disputes over state-directed payments be brought to the Departmental Appeals Board. Nothing in the statute requires that result, and the court found that CMS could not limit access to federal courts in the absence of clear congressional authorization.

Finally, the court held that CMS' attempt to interpret § 1396b(w)(4)(C) to reach private arrangements also implicates the "major questions" doctrine, in light of the economic significance of state-directed payments and the fact that they represent a substantial amount of state and federal spending. The court reasoned that, even if CMS' reading were plausible, the agency had not identified clear congressional authorization for the final rule.

Final Rule Was Arbitrary and Capricious

The court also concluded that the final rule was arbitrary and capricious because CMS did not acknowledge or explain a change in policy. Texas identified prior CMS statements showing that the agency had long viewed the hold-harmless prohibition as applying only when the state implemented a guarantee.

In prior rulemaking and internal decisions, the court noted that CMS had understood the hold-harmless prohibition to apply when the state implemented a hold-harmless feature. In 2008, for example, CMS emphasized that it was applying a largely objective analysis by prohibiting federal financial participation for health care-related taxes "where the state has implemented a hold harmless provision." CMS had also previously indicated that it lacked authority to treat purely private arrangements as hold-harmless provisions.

Rather than recognizing that it was changing course, CMS asserted that its interpretation had not changed. The court held that the Administrative Procedure Act requires an agency to confront and explain any shift in its position, particularly when states may have relied on the prior interpretation. CMS' failure to do so was a sufficient basis for vacating the rule.

Remedy

The court vacated the challenged portions of the final rule and both informational bulletins. It also issued a permanent injunction preventing CMS from enforcing the interpretation of the hold-harmless statute.

CMS argued that any relief should be limited to Texas, but the court rejected that approach, relying on Fifth Circuit precedent that declined to limit relief where doing so would undermine national uniformity and predictability under a challenged agency action.

Practical Implications for Providers and States

For providers and states, the immediate practical effect of the decision is that CMS may not, at least for now, use the vacated final rule and bulletins to condition federal financial participation on states' regulation of private redistribution arrangements among providers or to require provider attestations concerning such arrangements as a condition of participating in state-directed payment programs. Accordingly, the decision has implications beyond Texas. Because the court vacated the challenged provisions rather than issuing only party or state-specific relief, the decision is relevant in any state that uses provider taxes, local provider participation funds, or

similar mechanisms. States and providers in those jurisdictions may view the decision as confirming that federal law does not, at this point, extend the hold-harmless prohibition to private redistribution arrangements.

The Texas district court's decision is particularly consequential when viewed alongside the Florida proceedings, which denied preliminary injunctive relief as to the 2023 bulletin based on Florida's failure to demonstrate a substantial likelihood of success on the merits. Notwithstanding the Florida outcome, CMS remains subject to a nationwide injunction barring enforcement of the challenged interpretation given the fact that the Texas district court permanently enjoined CMS from enforcing the interpretations found in the final rule and the 2023 and 2024 informational bulletins (notably, the Eleventh Circuit did not cite or otherwise address the recent Texas decision). It remains to be seen how CMS will reconcile these decisions and proceed in light of the nationwide injunction.

However, the Texas decision should preserve existing financing structures that rely on provider taxes and local provider participation funds, as long as those structures comply with the statutory requirements that the taxes be broad-based and not include state-provided hold-harmless guarantees. Moreover, the ruling eliminates, at least for now, several administrative burdens associated with the 2024 final rule. States are no longer required to ensure that providers receiving state-directed payments submit attestations about their participation in hold-harmless arrangements, and CMS may not treat purely private redistributions as disqualifying hold-harmless provisions under the vacated interpretation. That may reduce some of the compliance and documentation pressure on providers and state agencies that were preparing to adjust to the new requirements.

At the same time, the broader policy environment suggests that Medicaid financing will continue to receive attention from CMS and Congress. The court noted that state-directed payments represent a substantial amount of state and federal spending. Recent federal legislation, including provisions of the One Big Beautiful Bill Act, has also drawn attention to provider taxes and Medicaid financing mechanisms. Providers should, therefore, continue to monitor developments in this area, including CMS' pending appeal of the district court's decision. The Fifth Circuit will have the opportunity to review the district court's findings and either affirm or reverse the court's holding.

Conclusion

The district court's decision is an important development for states and providers that rely on provider taxes and supplemental payment programs. By vacating CMS' 2024 final rule (i.e., [42 C.F.R § 438.6\(c\)\(2\)\(ii\)\(G\)](#) and [42 C.F.R § 438.6\(c\)\(2\)\(ii\)\(H\)](#)) and related 2023 and 2024 bulletins and by enjoining CMS from enforcing its expanded interpretation of the hold-harmless statute, the district court has reaffirmed the limits of CMS' statutory authority and preserves, at least in the near term, the status quo for states and providers that rely on provider taxes and local provider participation funds.

Although CMS has appealed, the district court's ruling governs for now. The court's decision ensures that existing provider tax and supplemental payment arrangements may continue without the additional conditions CMS sought to impose.

Providers and states should, however, remain attentive to the appeal and to any further activity in this area, as Medicaid financing mechanisms continue to draw federal attention. The decision arrives during a period of heightened scrutiny of Medicaid funding mechanisms. Provider taxes, supplemental payments, and state-directed payments are likely to remain a focus of both regulatory and legislative activity.

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CMS Finalizes Changes to Hospital Price Transparency in CY 2026 OPPS Final Rule

Final rule effective Jan. 1, but CMS to delay enforcement of revisions until April 1

By Ahsin Azim

The Centers for Medicare and Medicaid Services finalized proposed changes to hospital price transparency requirements in the calendar year 2026 hospital outpatient prospective payment system final rule, issued Nov. 21, 2025. Changes in the 2026 OPPS final rule include:

- Updates to the data elements required in the machine-readable file,
- An updated affirmation statement, and
- Enhanced enforcement mechanisms.

These changes are explored further in this article. To aid compliance, CMS has published several helpful tools on its website. The comprehensive list of resources is available at <https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/resources>.

Overview of Hospital Price Transparency Rule

The hospital price transparency rule took effect Jan. 1, 2021. The following overview outlines the core requirements of the rule, enforcement to date, and the new administration's stance that hospital price transparency is a priority.

Core requirements

The hospital price transparency rule requires hospitals to publish five types of standard charges for each item and service. The required five types of standard charges include:

- Gross charges (i.e., the chargemaster),
- Discounted prices that apply to patients who pay cash,
- Payer-specific negotiated rates,
- The de-identified minimum charges that a hospital has negotiated with third-party payers, and
- The de-identified maximum charges that a hospital has negotiated with third-party payers. [45 C.F.R. § 180.20.]

Hospitals must publish this data in two forms:

1. In a single comprehensive machine-readable file with all standard charges established by the hospital for all the items and services it provides; and
2. In a consumer-friendly display of standard charges for as many of the 70 CMS-specified shoppable services that are provided by the hospital and as many additional hospital-selected shoppable services as are necessary, for a combined total of at least 300 shoppable services. [45 C.F.R. § 180.40. The final list of 70 CMS-specified shoppable services is available at <https://www.cms.gov/files/document/steps-making-public-standard-charges-shoppable-services.pdf>.]

Hospitals may substitute a price estimator tool that meets certain regulatory requirements for the consumer-friendly display of shoppable services. [See 45 C.F.R. § 180.60.]

Enforcement to Date

Since the hospital price transparency rule took effect, CMS has thrice enhanced its enforcement processes to address a trend toward hospitals' high rate of noncompliance with the rule. The first set of changes was made in the CY 2022 OPPS final rule, 86 Fed. Reg. 63,458 (Nov. 16, 2021). The second set of changes was made through guidance published on CMS' website. [Centers for Medicare and Medicaid Services, Section on Newsroom, *Fact Sheet: Hospital Price Transparency Enforcement Updates* (April 26, 2023), <https://www.cms.gov/newsroom/fact-sheets/hospital-price-transparency-enforcement-updates>.] The third set of changes was made in the CY 2024 OPPS final rule, 88 Fed. Reg. 81,540 (Nov. 22, 2023).

If CMS concludes that a hospital is noncompliant with one or more of the requirements of the hospital price transparency rule, CMS may take any of the following actions, which typically will occur in the following order:

- *Warning letter*: CMS will provide a written warning notice to the hospital with instructions to correct the deficiencies within 90 days of the specific violation(s).
- *Corrective action plan*: If a hospital does not come into compliance after 90 days, CMS will issue a corrective action plan request with a 45-day deadline for hospitals to submit a corrective action plan. Hospitals must be in full compliance within 90 days from when CMS issues the corrective action plan request. Furthermore, if a hospital has not made any attempt to satisfy the requirements of the hospital price transparency rule, CMS will immediately request that the hospital submit a corrective action plan without first issuing a warning letter.
- *Civil monetary penalty*: CMS will impose a civil monetary penalty on a hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a corrective action plan at the end of the 45-day submission deadline or fails to comply with the terms of the corrective action plan by the end of the 90-day deadline.

CMS most recently increased civil monetary penalties for noncompliance in the CY 2022 OPPS final rule and now applies a scaling factor. A hospital's maximum daily penalty will scale based on the number of beds reported by the hospital in its most recently settled Medicare cost report. The civil monetary penalty scaling factor by bed size:

- \$300 per day for a hospital with 30 beds or less (annual maximum of \$109,500);
- \$310 to \$5,500 per day (\$10/bed/day) for hospitals with 31 to 550 beds (annual maximum of \$113,150 to \$2,007,500); and
- \$5,500 per day for a hospital with more than 550 beds (annual maximum of \$2,007,500).

To date, CMS has imposed civil monetary penalties on 27 hospitals for noncompliance, ranging from as low as \$32,301 to \$871,122. [Centers for Medicare and Medicaid Services, Section on Hospital Price Transparency, Enforcement Actions (last updated Nov. 3, 2025), <https://www.cms.gov/hospital-price-transparency/enforcement-actions> .]

CMS issued these civil monetary penalty notices for a variety of reasons, including:

- Failure to make public a machine-readable file containing a list of all standard charges for all items and services online as required at 45 C.F.R. § 180.40(a) and 45 C.F.R. § 180.50(a).
- Failure to make available a consumer-friendly list of standard charges for a limited set of shoppable services described in 45 C.F.R. § 180.60, as required by 45 C.F.R. § 180.40(b).
- Failure to include all corresponding data elements in the list of standard charges, as applicable, as provided in 45 CFR §180.50(b).
- Failure to follow the naming convention specified by CMS, specifically: __standard charges.[json|xml|csv] as required at 45 CFR §180.50(d)(5).
- Failure to update the standard charge information described in 45 CFR §180.50(b) at least once annually as required at 45 CFR §180.50(e).

The civil monetary penalty notices also describe the timing of CMS' initial review, CMS' initial outreach to the hospital to correct violation(s), and any subsequent communications between CMS and the hospital, including who CMS contacted, the extension numbers CMS called, and the response (or lack of response) the hospital provided CMS. The public list of enforcement actions is available at <https://www.cms.gov/hospital-price-transparency/enforcement-actions> .

Hospitals have 60 calendar days from the date of notice to pay a civil monetary penalty. A hospital may appeal CMS' civil monetary penalty determination by requesting a hearing before an administrative law judge of the Department of Health and Human Services Departmental Appeals Board. To request a hearing, the hospital must submit its hearing request within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty.

A Priority for the Executive Branch

On Feb. 25, 2025, President Donald Trump issued an executive order directing the Department of the Treasury, Department of Labor and HHS to implement and enforce existing price transparency regulations, including the hospital price transparency rule. [The White House, Section on Presidential Actions, *Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information* (Feb. 25, 2025), <https://www.whitehouse.gov/presidential-actions/2025/02/making-america-healthy-again-by-empowering-patients-with-clear-accurate-and-actionable-healthcare-pricing-information/>.]

The executive order states: "By building on the historic efforts of my first term, my Administration will make more meaningful price information available to patients to support a more competitive, innovative, affordable, and higher quality healthcare system." The executive order directed the three federal departments to:

- Ensure hospitals and insurance issuers disclose actual prices and not estimates;
- Take action to make prices comparable across hospitals and insurance issuers, including drug prices; and
- Update their enforcement policies.

Subsequently, on April 10, 2025, CMS Administrator Dr. Mehmet Oz shared his vision for CMS, which included effectuating the executive order:

We aim to mark our Make America Healthy Again efforts with curiosity, courage, competence, and compassion. Under his leadership, CMS will work to modernize Medicare, the Marketplaces and Medicaid, so Americans get the care that they want, need, and deserve. This includes ... [e]mpowering the American People with personalized solutions they can better manage their health and navigate the complex health care system. As a first step, CMS will implement the President's Executive Order on Transparency to give Americans the information they need about costs. [Centers for Medicare and Medicaid Services, Section on Newsroom, Press Releases, *Dr. Mehmet Oz Shares Vision for CMS* (Apr. 10, 2025), <https://www.cms.gov/newsroom/press-releases/dr-mehmet-oz-shares-vision-cms>.]

The executive order drives the changes to the hospital price transparency requirements in the 2026 OPPS final rule.

Finalized Changes in the 2026 OPPS Final Rule

Finalized changes and updates in the 2026 OPPS final rule include three new data elements, other machine-readable file updates, enforcement updates and effective date. Additional details for these changes and updates are outlined below.

Three new data elements

Under the prior iteration of the hospital price transparency rule, when the standard charge was based on a percentage or algorithm, the hospital was required to encode the "estimated allowed amount" in dollars for that item or service in the machine-readable file. The estimated allowed amount is the "average dollar amount that the hospital has historically received from a third-party payer for an item or service." [45 C.F.R. § 180.20.]

Under the CY 2026 OPPS final rule, CMS finalized its proposal to replace the requirement to encode the estimated allowed amount with the following three new data elements:

- **Median allowed amount.** Defined as the median of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the

12 months prior to posting the machine-readable file. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.

- **Tenth (10th) percentile allowed amount.** Defined as the 10th percentile of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value.
- **Ninetieth (90th) percentile allowed amount.** Defined as the 90th percentile of total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

The total allowed amount figure used in each of these definitions is derived from the gross charge minus contractual adjustments and consists of the portion billed to a payer for a particular plan and the portion, if any, billed to the patient. The amount should reflect the total amount the hospital was reimbursed for the item or service (or service package). CMS requires that hospitals determine the 'total allowed amount' from EDI 835 electronic remittance advice transaction data from no longer than 12 months prior to posting the machine-readable file.

Other machine-readable file updates

The prior iteration of the hospital price transparency rule required each hospital to affirm in its machine-readable file that the hospital, to the best of its knowledge and belief, has included all applicable standard charge information in accordance with the requirements of 45 C.F.R. Part 180, and that the information displayed is true, accurate and complete as of the date indicated in the file. The CY 2026 OPPS final rule supplants the existing affirmation statement as follows:

- Beginning Jan. 1, 2026, hospitals are required to include in their machine-readable files the following attestation: "The hospital has included all applicable standard charge information in accordance with the requirements of § 180.50, and the information encoded is true, accurate, and complete as of the date in the file. The hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the [machine-readable format] or [are] not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula."
- Beginning Jan. 1, 2026, hospitals must encode the name of the hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data as directed in § 180.50(a)(3)(iii).
- Separately, beginning Jan. 1, 2026, hospitals must report a unique identifier, specifically their national provider identifier(s), in the machine-readable file. As background, Executive Order 14221 directed HHS to ensure that pricing information was standardized across hospitals and health plans. Accordingly, CMS, in the CY 2026 OPPS final rule, requires that hospitals encode their organizational, or Type 2, national provider identifier(s), or NPIs, in the machine-readable files, or MRF. "Hospitals will be required to report, in a newly created general data element in the MRF, any Type 2 NPI(s) that is associated with primary taxonomy code starting with '28' (indicating hospital) or '27' (indicating hospital unit) and that is active as of the date of the most recent update to the standard charge information." [Centers for Medicare and Medicaid Services, Section on Newsroom, Fact Sheet, CY 2026 OPPS and Ambulatory Surgical Center Final Rule - Hospital Price Transparency Policy Changes (Nov. 21, 2025), <https://>

www.cms.gov/newsroom/fact-sheets/cy-2026-opps-ambulatory-surgical-center-final-rule-hospital-price-transparency-policy-changes .

Enforcement updates

Under current hospital price transparency regulations, hospitals can appeal a civil monetary penalty within 30 days of issuance of the civil monetary penalty notice. The CY 2026 final rule now allows a civil monetary penalty to be reduced by 35% should a hospital submit to CMS a written notice requesting to waive its right to a hearing under § 180.100 within 30 calendar days of the date of the notice of imposition of the civil monetary penalty.

The final rule also requires that if a hospital waives its right to appeal a civil monetary penalty and receives a 35% percent reduction in the penalty amount, the hospital:

- Will not be eligible to receive a 35% reduction on any civil monetary penalties issued that result from the same instance(s) of noncompliance (i.e., continuing violations); and
- Will waive its right to appeal civil monetary penalties for any such continuing violations.

The final rule also implements CMS' proposal that the agency decline to make available to hospitals the opportunity to have a civil monetary penalty amount reduced in certain situations. These include:

- When a hospital has not affirmatively waived its right to a hearing in accordance with the procedures specified at proposed § 180.90(c)(4); and
- When CMS imposes upon a hospital a civil monetary penalty for noncompliance going to the core of the hospital price transparency requirements — for example, failing to make public either a machine-readable file, as required in 45 C.F.R. § 180.40(a), or any shoppable services in a consumer-friendly format (either in the form of a shoppable services file or an internet price estimator tool), as required in 45 C.F.R. § 180.40(b) — the hospital will be ineligible to avail itself of such an opportunity.

Effective date

Although the 2026 OPPS final rule is effective Jan. 1, 2026, CMS delayed enforcement of these finalized revisions until April 1, 2026. This three-month enforcement delay will apply solely to enforcement actions based on the new CMS requirements summarized in this article. CMS believes that this enforcement delay will provide hospitals with time to update their systems and to review, validate and post their files.

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