LEGAL UPDATES

# Flying Through the Whirlwind: Health Care Industry Continues To Be Buffeted as Administration Rolls Out New Initiatives

04/09/2025 | 9 minute read

Health care providers and payers have been subject to a flurry of developments at the federal level in recent weeks. Considering that health care represents almost 18% of the U.S. gross domestic product, this was perhaps inevitable – particularly in light of disruptions that have affected other sectors of the economy. But with tight margins and a complex regulatory environment, providers and payers are left facing a degree of uncertainty not felt since the early days of the COVID-19 pandemic. Outlined below is a sampling of key changes from recent days.

## HHS Reorganization and Reduction in Force

At the end of March, the U.S. Department of Health and Human Services (HHS) announced a "dramatic restructuring" pursuant to President Trump's February 11 Executive Order, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative." While the precise parameters of this restructuring continue to evolve, announced changes include:

- Creation of a new "Administration for a Healthy America," which combines a number of existing HHS components – including the Health Resources Services Administration, the Substance Abuse and Mental Health Services Administration, the National Institute for Occupational Safety and Health, and several others – into a new entity.
- Designation of a new "Assistant Secretary of Enforcement," with authority to oversee the HHS Departmental Appeals Board, Office of Medicare Health and Appeals, and Office for Civil Rights. The purpose of this role is to "combat waste, fraud and abuse" in federal health care programs.
- HHS regional offices will be consolidated, reducing the total number from 10 to 3.

Meanwhile, approximately 20,000 people are being let go from HHS and its various divisions. This means, for example, that the Food and Drug Administration (FDA) will see the departure of roughly 3,500 employees, the Centers for Disease Control (CDC) will lose about 2,400 workers, the National Institutes of Health (NIH)

## Related People


**Jesse A. Berg**
Partner

Minneapolis

612.632.3374

jesse.berg@lathropgpm.com


## Related Services

Navigating the Second Trump Administration: Executive Orders & the Changing Legal Landscape

## Related Sectors

Health Care

Health Care Regulatory & Compliance Counseling

will need to make do with 1,200 fewer workers, and the Centers for Medicare & Medicaid Services (CMS) will see a decrease of about 300 employees.

Terminations apparently began on April 1, though HHS has reportedly backtracked on some of these cuts already, at least in part because certain personnel may have been let go by mistake. The cuts are controversial for another reason, however – because they involve significant reductions in force from agencies that have already been tasked and funded by Congress to carry out specific statutory mandates. The question of whether authority exists to implement this downsizing is sure to be hotly litigated. And while the Trump Administration has indicated that core agency functions will not be jeopardized, others, including a former FDA commissioner, have pushed back on that claim.

## "Pharmaceuticals" Are Exempt (for now) from Tariffs … But What About Other Inputs?

The administration issued an Executive Order on April 2 providing more detail about the tariffs announced earlier that day. The order noted that "pharmaceuticals" would be exempt. It also included an accompanying "Annex II," which offered more detail about the various categories of products (including certain compounds and drugs) that would not be subject to the tariffs.

However, the scope of the "pharmaceutical" exclusion is murky. For example, some of the ingredients, chemicals, equipment and other materials that manufacturers need to make drugs are not included on the list of exempt items. Moreover, the administration has reportedly indicated that a number of manufacturing sectors, including the pharmaceutical industry, will be subject to specific tariffs in the future, hinting, for example, at a 25% rate. Of course, drugs are but one component of health care delivery and providers rely on complex supply chains for many of the supplies, technology, equipment and other inputs needed for patient care. This is part of the reason that various industry groups have been lobbying the administration to exempt certain products, like medical devices made in China and other countries, from the tariffs. To date, these efforts have not been successful.

Meanwhile, a recent survey of 200 health care executives suggests considerable concern exists in terms of what the tariffs are likely to mean for health care. According to publicly available information, 88% of the executives forecasted a minimum 18% increase in the costs of medical equipment by the end of the year, while 97% believed that there would be an increase of at least 15% in pharmaceutical expenses. In addition, 83% of respondents indicated that they were in "emergency budget recalibration mode." On the issue of how to handle increased costs, 95% of payer executives reportedly indicated that claims cost inflation will lead to "double digit" increases in insurance premiums, while 75% of provider executives indicated that they were planning on shifting costs to payers and patients.

## Payment Rates in Medicare Advantage Increase; Will Need to Wait Until Spring/Summer for Traditional Medicare

The recently released 2026 Medicare Advantage final rule will increase payment to Medicare Advantage plans by 5.06% from 2025 to 2026. This represents a significant uptick from the payment rates outlined in a proposed rule issued by the Biden Administration in its waning days, which would have increased by payment by 2.2%.

While this is good news for Medicare Advantage Organizations (MAOs), and potentially the health care providers who see substantial volumes of Medicare Advantage enrollees, payment rates under Part B of the Medicare program (which covers physician and related services) saw a reimbursement cut of 2.93% for 2025 under the Medicare Physician Fee Schedule (MPFS) that came out in early December 2024. CMS updates payment annually for all provider and supplier categories, with critical proposed rules generally issued in April (inpatient hospital) and July (MPFS and hospital outpatient). Providers and suppliers will want to watch for those proposed rules and take advantage of the opportunity to provide comment to CMS on meaningful reimbursement and other policy changes.

## Nursing Home Staffing Mandate Struck Down in Texas, While Administration Defends It in Iowa – What Does the Future Hold?

In May 2024, CMS released regulations that, for the first time, established minimum staffing levels for Medicare- and Medicaid-certified long-term care facilities. Nursing homes would be obligated to meet minimum nurse staffing requirements, ensure the presence of a registered nurse (on a 24/7 basis) and meet enhanced facility assessment requirements. The change was controversial because some facilities argued that it would be challenging to comply with the new requirement of ensuring total nurse staffing of at least 3.48 hours per resident day. Among other things, the facilities contended that it is already difficult to find and retain sufficient staff, and expressed a concern that the CMS guidelines were likely to push many facilities out of business. Several nursing homes, along with various industry associations, filed suit challenging CMS's ability to impose the staffing mandate.

On April 6, a federal judge in Texas tossed out the staffing mandate, finding that the new regulatory requirements exceeded CMS's authority. In making his decision, Judge Kacsmaryk wrote that, while the staffing mandate was "rooted in laudable goals," any regulatory response to deficiencies in nursing home care must be "consistent with Congress' legislation governing nursing homes." Interestingly, this decision comes on the heels of the administration filing a brief in a different case the first week of April (in the Eighth Circuit Court of Appeals) defending the same staffing mandate that was vacated in the Texas case. The administration's filing argued that the U.S. Court of Appeals should deny a preliminary injunction against the mandate sought by a coalition of nursing homes, state attorneys general and various industry associations. All of this has infused new uncertainty about the future of the staffing mandate.

## Cancellation of Value-Based Care Models

On March 12, CMS announced the elimination and early termination of several alternative payment models currently operated by the Center for Medicare and Medicaid Innovation (CMMI). The models at issue were all scheduled to run through specified dates (noted below). However, CMMI made the decision to end them early because of a need to "align [payment models] with … statutory obligations and strategic goals." Models slated for early termination include:

- Maryland Total Cost of Care (2019-2026)
- Primary Care First (2021-2026)
- ESRD Treatment Options (2021-2027)
- Making Care Primary (2024-2034)

CMMI also announced that it is considering options to reduce the size of the Integrated Care for Kids program (2020-2026). Further, the agency will no longer pursue two previously announced, but not yet implemented, models: Medicare $2 Drug List and Accelerating Clinical Evidence.

CMMI has run dozens of "value-based" or "outcomes-based" payment models since the Affordable Care Act was passed in 2010. In general, these models are intended to break down silos of care and communication barriers that impede collaboration and incentivize providers (and often payers) to achieve positive results like reduced costs or improved outcomes through targeted financial incentives. They are often geared toward areas of demonstrable need, like primary care. Importantly, CMMI stated that its other active models are consistent with the "statutory mandate" and will thus continue.

## Do Fights Over Grant Funding Portend Increased Scrutiny of Research?

The HHS Office of Inspector General (OIG) issued a report in late March asserting that only 19% of NIH grant recipients "correctly identified" all scenarios in which they were required to report monetary donations and other financial support received from other sources. As a condition of receiving NIH research grants, investigators are required to disclose other funding that they receive – the goal is to ensure NIH grant resources do not duplicate other kinds of support. In its report, the OIG pointed out that investigators have often failed to disclose financial contributions related to research that they received, including donations from "foreign governments." Failure to disclose financial contributions can lead to enforcement actions, including disallowing costs, withholding further awards and suspension/termination of grant funding.

The OIG's report coincides with multi-front efforts by the administration to terminate or significantly reduce the scope of research funding from NIH and other agencies. This has led to a struggle among state and federal governments, research institutions, academic centers and others. On April 4, for example, 16 states sued the Trump Administration based on its efforts to withhold NIH grant funding from medical and public health research agencies. The suit alleges that the administration "has engaged in a concerted, and multi-pronged effort to disrupt NIH's grants," including through "across the board delays in the review and approval of otherwise-fundable grant applications and widespread termination of already-issued grants." Meanwhile, in an unrelated case, a Massachusetts district court issued a permanent injunction last week against the administration's efforts to significantly reduce indirect research costs through imposition of a 15% cap; that injunction is likely to be appealed. Regardless of what happens in these and other battles related to the future of NIH grants, the recent OIG report may hint that federal regulators will be applying increased scrutiny to grant recipients.

## Pricing Transparency Remains Elusive but Important

Providers and payers have long been subject to an array of federal and state obligations geared toward creating transparency for consumers by making pricing and reimbursement information more accessible and understandable. For example, since 2021, hospitals have been required to make public a machine-readable file containing a list of all standard charges for items/services, as well as a consumer-friendly list of standard charges for shoppable services.

Compliance with, and enforcement of, these requirements has been haphazard at best. In response, CMS started cracking down on providers' failure to make pricing information available in 2023. Among other things, the agency indicated it would:

- require full compliance within 90 days from a corrective action plan (CAP) request (hospitals had been previously allowed to propose a CAP completion date);
- automatically impose civil monetary penalties for failure to submit a CAP within 45 days and failure to comply with the CAP within 90 days; and
- immediately request a CAP for hospitals that make no attempt to satisfy applicable requirements (the previous approach had been to send a warning letter).

An Executive Order issued in late February directs various agencies, including HHS, to take steps to "rapidly implement and enforce" various health care transparency requirements, including:

- requiring the disclosure of "actual" prices (as opposed to estimates); and
- issuing updated guidance or proposed regulatory action to ensure "pricing information is standardized and easily comparable" across hospitals and payers.

The Executive Order gives the agencies until May 26, 2025, to take these steps.

## No Adoption of Guardrails for Artificial Intelligence to Ensure Equitable Access to Medicare Advantage Services

In November 2024, the Biden Administration released the 2026 Medicare Advantage proposed rule, which included a requirement designed to prevent algorithmic discrimination in artificial intelligence (AI)-based health care. CMS explained in the rulemaking that while AI has generated efficiencies, there "have been many instances of algorithmic discrimination, where the use of AI has resulted in deepening bias and discrimination, exacerbating existing inequities within the health care system." The rule proposed to adopt a new regulation that would have required Medicare Advantage organizations to ensure that services are provided equitably, "irrespective of delivery method or origin, whether from human or automated systems." CMS explained that if MAOs use AI tools in any manner, it is their responsibility to ensure that the usage of such tools provides "culturally competent care to all enrollees in a non-discriminatory manner."

The new administration took a different approach when it issued the 2026 Medicare Advantage final rule. That rule, which was released on April 7, 2025, noted that CMS elected not to adopt this nondiscrimination provision for AI. CMS did not elaborate on its decision in that regard, observing that it does "acknowledge the broad interest in regulation of AI and will continue to consider the extent to which it may be appropriate to engage in future rulemaking in this area."

## Withdrawal of Medicare Coverage for GLP-1 Weight Loss Drugs

In 2024, HHS announced that Medicare and Medicaid would expand coverage of certain anti-obesity medications (AOMs), commonly known as GLP-1 drugs, like Ozempic® and Wegovy®. This change was expected to expand coverage to roughly 3.4 million enrollees of the Medicare Part D program who have obesity and had been forced to cover the costs of those drugs out of pocket. In announcing this shift in 2024, the agency stated that most manufacturers of anti-obesity medications "have been steadily raising U.S. list prices for AOMs on or entering the market in 2017," and that prices in this country are "significantly higher than in comparator countries."

On April 4, 2025, however, HHS changed course in a final rule it released that day making changes to the Medicare Part D program. Among other things, the final rule indicated that Medicare and Medicaid would not expand coverage of these medications. There may, however, be some divergence of opinion among health policy leaders in the current administration related to the value of these drugs in fighting obesity. Whereas HHS Secretary Kennedy has indicated the first line of response to obesity should be "lifestyle," newly minted CMS Administrator Oz has noted that the "amount of good done by these medications by helping people lose weight … is massive."

Our health care team will continue to monitor these and other industry developments. If you have questions about potential impacts on your business, please contact Jesse Berg, or your regular Lathrop GPM attorney.