Preparing for Healthcare's Regulatory Environment Shift

Healthcare providers are approaching a major regulatory shift. On May 11, the Federal Public Health Emergency (PHE) for the COVID-19 pandemic will lapse, ending or sunsetting regulatory changes which greatly benefited providers during the pandemic.

The end of the PHE, along with other impending changes to Medicare and Medicaid, will result in an increased compliance and financial burden for providers. To prepare for the coming regulatory shift, providers must understand what will change, what will stay the same and how new regulations will impact them specifically.

End of the **PUBLIC HEALTH EMERGENCY**

PHE made pandemic-era care delivery easier by temporarily relaxing certain regulations and providing more federal money for COVID-19 treatment. Medicare payments were increased by 20% for inpatient COVID-19 admissions, and the sunsetting of this funding will coincide with millions losing access to temporarily expanded Medicaid coverage. In short, treating COVID-19 will become more expensive for hospitals and patients. While some states will take steps to make Medicaid coverage more accessible and fill the reimbursement gap for COVID-19 treatment, many providers are still likely to see an increase in bad debt.

In addition, private insurance will no longer be required to cover COVID-19 testing without cost sharing, and many liability protections from the Public Readiness and Emergency Preparedness Act will sunset in 2024. These changes could make providers less resilient to new waves of COVID-19, especially should people decide to forgo testing due to cost.

Not all changes that stem from the end of the PHE have been set in stone yet. The FDA is still evaluating which industry guidance documents affecting clinical practice and supply chains will be extended or ended. Providers can also expect new rules to allow for some dispensing of controlled substances via telemedicine, a practice which is currently scheduled to end.

Fortunately, many Medicare and Medicaid telehealth flexibilities will not be impacted, and states have the option to allow Medicaid to continue covering all COVID-19 vaccinations and treatment through September 30, 2024. Perhaps most importantly, the FDA's emergency use authorizations for COVID-19 test, treatments and vaccines will not be impacted, and the federal government will remain committed to providing access to COVID-19 healthcare.

Regulatory Changes **ON THE HORIZON**

As the United States pivots from a COVID-19 emergency, providers need to be aware of big changes coming to Medicare and Medicaid. While regulatory changes will increase compliance burdens and could decrease reimbursements, these updates will particularly impact hospitals who are already struggling financially.

MedPAC proposes transforming hospital payments

A new Medicare Safety-Net Index could replace the disproportionate share hospital (DHS) payment system and uncompensated care payments in 2024. Proposed by the Medicare Payment Advisory Commission (MedPAC), this new system was designed to improve Medicare profitability for hospitals with low-income, high Medicare patient populations.

According to the **Healthcare Financial Management Association** (HFMA), The Safety Net Index payment system includes a few key changes:

- Compensations for claims filed for Part D low-income subsidy beneficiaries will be based on the hospital's share of inpatient and outpatient claims.
- Uncompensated care costs will now be counted as a share of revenue.
- Medicare will reduce its share of coverage of a hospital's inpatient days by half.

While well-intentioned, this new index may negatively impact reimbursements for Safety-Net hospitals that treat large, low-income patient populations where most patients are not covered by Medicare.

CMS Transmittal 18 brings increased **COST REPORTING COMPLEXITY**

New requirements for Medicare bad debts and Uncompensated Care Cost reporting will require hospitals to submit more detailed demographic and payment data. The Centers for Medicare & Medicaid Services (CMS) have issued new templates, additional worksheets and new instructions which will impact how hospitals report charity discounts, bad debt and Medicaid eligible days.

These requirements came into force for cost reporting periods beginning on or after October 1, 2022, and the first reports that will actually encounter these news complications are those than end on September 30, 2023.

Providers should be aware that Transmittal 18's new requirements will significantly increase hospital compliance burdens. While failure to comply will result in cost report rejections, increased risk of an audit and lower Medicare and Medicaid reimbursements, the risk of failure will be highest when the first reports are due. To avoid mistakes, hospitals should study Transmittal 18 now and design a plan to meet the new reporting requirements come September.

CMS announces 340B
ACQUIRED DRUGS CHANGES

Medicare will be required to pay 340B hospitals for Part B drugs and biologics at average sales price (ASP) plus an additional 6%. This reimbursement is being reinstated for Medicare, which in the past was ASP minus 22.5%. The result of this change is a nearly 30% increase in reimbursements for Part B medication.

This win for 340B hospitals comes at the cost of the Outpatient Prospective Payment System (OPPS) rate increase for FY 2023, which rose to 3.8%. 340B payments are supposed to be budget neutral, so the increase in 340B reimbursements will be offset by a CMS budget adjustment of 3.09%. As a result, CMS estimates that the OPPS payment rate will only see a real increase of 0.9%. This minor increase for OPPS has led some hospitals to believe that this CMS change won't do much ease their growing cost of care burden.

Potential Regulations **TO WATCH**

The CMS Equity Framework

2024 in-patient rules from CMS will be released in mid-April 2023, which will include key metrics based on the 2022-2032 CMS Framework for Health Equity. The metrics will be designed to help hospitals reduce health inequity, and are expected to be more objective and quantitative than previous CMS metrics.

The latest CMS Framework for Health Equity outlines five priorities:

1. **Expand** the collection, reporting and analysis of standardized data.
2. **Assess causes of disparities** within CMS programs, and address inequities in policies and operations to close gaps.
3. **Build capacity** of healthcare organizations and the workforce to reduce health and healthcare disparities.
4. **Advance** language access, health literacy and the provision of culturally tailored services.
5. **Increase** all forms of accessibility to healthcare services and coverage."

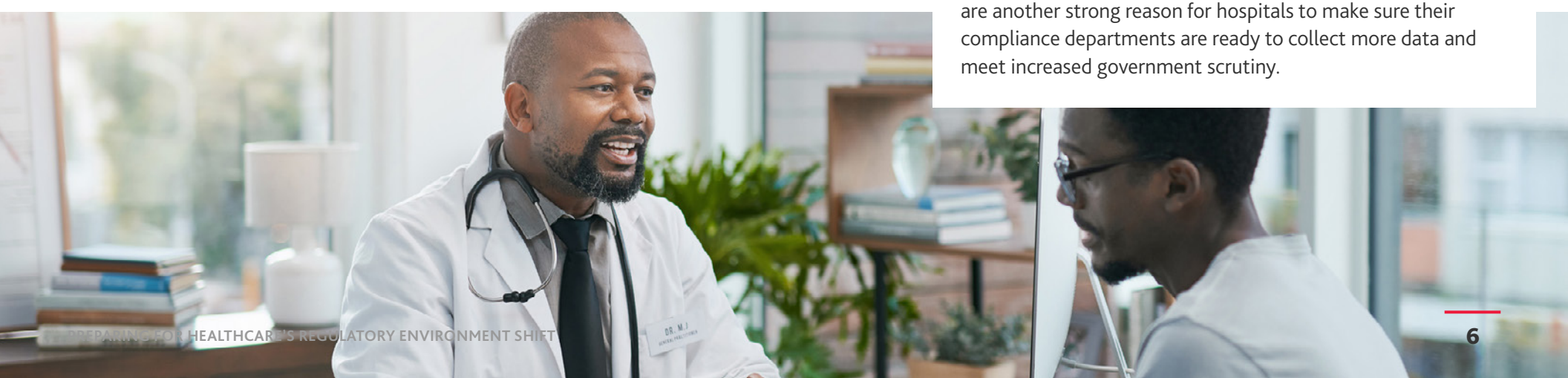
Hospitals should prepare to meet CMS' priorities, starting with developing strategies to collect data on patient outcomes. Signaling out health inequalities in a provider's patient population, and providing tangible metrics on progress, will be critical to maintaining compliance with future regulations related to equity.

OIG Medicare Bad Debts Report

Tougher Medicare bad debts reporting requirements may be on the horizon after an audit from the HHS Office of Inspector General (OIG). The organization randomly selected 67 cost reports and 148 samples of bad debts that totaled $450,687. Of those samples, OIG determined that CMS incorrectly reimbursed 22 bad debts to a cost of $29,787.

OIG believes that these reimbursements resulted from Medicare administrative contractors (MACs) who did not concentrate on reviewing bad debts when performing audits of costs reports. Additional bad debt reporting requirements could tamp down on unallowable Medicare reimbursements. Currently, hospitals are reimbursed for 65% of their bad debt, but a reduction in payments and increased compliance requirements could increase provider financial stress.

While not set in stone, Environmental, Social and Governance (ESG) and Medicare Bad Debts reporting requirements could greatly impact hospitals in the near future. Like the regulations that are currently on the horizon, these potential changes are another strong reason for hospitals to make sure their compliance departments are ready to collect more data and meet increased government scrutiny.



KEY TAKEAWAYS

With the end of the Public Health Emergency and the introduction of new Medicare and Medicaid regulations, providers may have a challenging road ahead. Greater compliance burdens and new regulations may lead to fewer reimbursements, and any increase in bad debt could coincide with lengthening payment cycles. Many hospitals don't have the cash reserves to take a financial shock like this.

For example, many small or rural hospitals may have to close or affiliate with larger health systems. Struggling hospitals who can stay independent may have to shutter less lucrative departments or shift offerings to serve more profitable patient populations. Hospitals who primarily serve low-income, non-Medicare patient populations should be especially attune to how coming changes to reimbursement policies will impact their ability to remain solvent.

All providers should explore how these changes, proposed and finalized, may impact their financial standing and take action now. Preparing today will allow hospitals to strategize on how they can provide the best care possible in the face of growing financial stress.

Looking to learn more about how these regulatory changes could impact you? Reach out to a BDO professional today to start a discussion.

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