PRESERVE AND PROTECT THE 340B PROGRAM

Enacted in 1992 and last expanded in 2019, Congress passed laws that established the 340B Drug Discount Program, which allows safety net providers to obtain discounts for certain drugs. It also requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to those providers. The law enables eligible hospitals that serve large numbers of low-income patients to stretch scarce federal resources and provide more comprehensive care to their patients and communities. More than 60 Missouri hospitals are participating in the 340B program.

Issue

The 340B program has been under attack for many years by pharmaceutical manufacturers that implement unilateral policies to restrict the number of eligible entity contract pharmacies. These tactics do nothing more than transfer the benefits intended for 340B-eligible providers onto themselves.

Operating Income	2020	2021	2022
Novartis (NVS)	20.3%	22.1%	17.7%
Pfizer (PFE)	20.9%	24.9%	37.1%
Merck & Co (MRK)	17.7%	27.1%	30.8%
Sanofi (SNY)	21.1%	23.3%	26.2%
GlaxoSmithKline (GSK	18.3%	19.6%	22.9%
AstraZeneca (AZN)	13.9%	-0.4%	10.3%
Missouri 340B Hospital Average	0.3%	2.1%	Not available

Implications

The 340B program does not cost the federal government anything while providing hospitals relief from high pharmaceutical costs and unreimbursed governmental payer cost. Even with the benefits of the 340B program, eligible Missouri hospitals realize very thin margins, averaging 2.1% in 2021. It is not uncommon for drug manufacturers to enjoy margins exceeding 20%, with some recently exceeding 30%. If pharmaceutical manufacturers succeed in reducing or eliminating the 340B benefits, hospitals will be forced to make up the difference through cost-shifting onto commercial business and reducing services that benefit the community, all while pharmaceutical manufacturers realize even higher margins.

1

Previous Actions

Although the Health Resources and Services Administration wrote strong letters reiterating its opposition to the pharmaceutical manufacturers' attacks, the agency has limits on its regulatory authority over 340B. The 117th Congress sent 'Dear Colleague' letters that urge the U.S. Department of Health and Human Services to begin assessing civil monetary penalties, require manufacturers to refund covered entities the discounts they have unlawfully withheld, stop any attempt to unilaterally change 340B upfront discounts and immediately seat the Administrative Dispute Resolution Panel to begin processing disputes within the program.

Recent Actions

The U.S. Court of Appeals for the Third Circuit recently issued a decision that upheld the lower court's finding that 340B drug manufacturers are not required to supply discounted medications to an unlimited number of contract pharmacies, adding that HHS incorrectly interpreted the law. While two other similar cases are pending decisions, Congressional action is needed to clarify the intent of the law so that 340B-eligible entities and contract pharmacies are protected. Representative Matthew Rosendale (R-Mont.) introduced the Drug Pricing Transparency and Accountability Act (H.R. 198). If enacted, the bill would place a two-year moratorium on eligible providers from adding contract pharmacies. The bill also would include restrictions to reduce the number of current contract pharmacies. MHA opposes the proposed legislation.

Request for Action

MHA urges members of Congress to propose legislation that will preserve the savings intended for 340B-eligible entities. MHA supports the PROTECT 340B Act (H.R. 2534), introduced by Representative Abigail Davis Spanberger (D-Va.), that ensures the equitable treatment of covered entities and pharmacies participating in the 340B Drug Discount Program.

2

ADVOCACY BRIEF

COVID-19 WAIVER EXTENSION

The Centers for Medicare & Medicaid Services waived numerous Medicare regulations during the COVID-19 pandemic, allowing hospitals and health systems to better prepare for and treat patients, especially during periods of surge. Through expanded use of telemedicine, fewer restrictions on patient transfers and reduced administrative burden, the health care system could adapt to changing conditions and resource demands. Those regulatory flexibilities demonstrated that hospitals can provide safe, effective care without many of the burdensome requirements imposed by CMS.

Issue

The Medicare waivers allowed hospitals and health systems to better coordinate treatment, direct patients to appropriate sites of care and improve the delivery of patient-centered care. Through exercise of the waivers, hospitals demonstrated that many regulatory requirements imposed by CMS not only are unnecessary, but actually impede the provision of efficient and effective care to Medicare beneficiaries and other patients. While Congress temporarily extended some of the regulatory flexibilities beyond the Thursday, May 11, expiration of the COVID-19 national and public health emergency declarations, others will expire on that date. Continuation of these flexibilities will allow hospitals to build on the process improvements developed during the pandemic and relieve overburdened health care providers from excessive regulatory requirements, allowing them to focus on delivering high-quality, personalized care.

Request for Action

The Missouri Hospital Association extend the following regulatory flexibilities that otherwise would lapse Thursday, May 11.

- » Regulation 42 CFR §485.620 requires that the aggregate length of stay in a critical access hospital be limited to 96 hours. See the "Withdraw the Critical Access Hospital 96-hour Physician Certification Rule" briefing paper for details.
- » The Social Security Act requires a three-day inpatient hospitalization before a beneficiary is eligible for Medicare coverage of inpatient skilled nursing facility services. This requirement was waived during the pandemic and allowed for expeditious transfer of patients from the hospital to a more appropriate care setting. It has proven to be cost-effective and patient-centered, and allows hospitals to focus on caring for patients who require acute levels of care.
- The Preadmission Screening and Resident Review is an assessment process to help establish the level of care and appropriate care setting for patients upon discharge. Absent the waiver, hospitals cannot transfer individuals to a long-term care setting until the process is complete. The waiver allowed the assessment to be performed postdischarge, thereby ensuring patients were not unnecessarily utilizing acute care resources when they were eligible for a lower level of care.

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MHA applauds the numerous legislative proposals that would extend the use of telemedicine after December 2024. MHA supports H.R. 134 introduced by Representative Vern Buchanan (R-Fla.) that would remove geographic requirements and expand originating sites for telehealth services, H.R. 635 introduced by Representative Matthew Rosendale (R-Mont.) that would permanently allow coverage of certain mental health services provided through telehealth including audio-only, and S. 731 introduced by Senator John Kennedy (R-La.) that would make permanent the preferred treatment of telehealth and other remote care services for purposes of health savings accounts.

Thank You: MHA thanks Congress for temporarily extending the hospital at home program and certain telehealth flexibilities enacted through the Consolidated Appropriations Act of 2023.

ADVOCACY BRIEF

WITHDRAW THE CRITICAL ACCESS HOSPITAL 96-HOUR PHYSICIAN CERTIFICATION RULE

Congress created the critical access hospital designation through the Balanced Budget Act of 1997 in direct response to increasing numbers of rural hospital closures. CAHs receive certain benefits, such as reimbursement based on Medicare's share of allowable cost, to ensure their financial viability, which in turn assures health care access and essential services to rural citizens. CAHs are vital to their communities as they provide health care services close to home.

Issue

Current law requires physicians to certify that patients receiving inpatient services at a CAH will be discharged or transferred to another hospital within 96 hours. The "96-hour rule" limits inpatient services received at a CAH that otherwise can be available to patients receiving care in a prospective payment system hospital. Historically, the Centers for Medicare & Medicaid Services considered the 96-hour certification a low enforcement priority and waived the requirement during the COVID-19 public health emergency. The waiver will end Thursday, May 11, when the COVID-19 national emergency and PHE declaration end.

Implications

Absent the waiver, CAHs would have been unable to care for many COVID-19 patients, substantially increasing the impact of patient surge on acute care facilities. According to the American Hospital Association's Rural Report, CAHs have a "challenging patient mix," serving rural populations who "are notably older, have higher rates of chronic diseases and have higher prevalence of multiple chronic conditions." Some patients whose care can be well managed by a CAH may require a length of stay exceeding 96 hours. Once the 96-hour rule waiver ends, CAHs no longer will be available to relieve demand on capacity-constrained suburban and urban hospitals.

Request for Action

The Missouri Hospital Association urges Congress to support and enact legislation that would permanently withdraw the 96-hour rule requirement.

Thank You: MHA thanks Representative Sam Graves (R-Mo.) for his leadership by introducing the Save America's Rural Hospitals Act (H.R. 833). Among other priorities, within Section 301, the bill would permanently eliminate the 96-hour rule. MHA also thanks Representative Adrian Smith (R-Neb.) for introducing the Critical Access Hospital Relief Act (H.R. 1565) that also would repeal the 96-hour rule.

OBTAINING ACCESS TO FEMA/SEMA FUNDING

Hospitals and providers faced unprecedented uncertainty while remaining open to serve patients during the COVID-19 pandemic. To help with the uniquely difficult fiscal issues caused by the pandemic, Congress wisely acted to provide financial support. The Missouri Hospital Association's member hospitals express gratitude for the COVID-19 national emergency assistance provided to hospitals throughout Missouri. The Paycheck Protection Program, the Medicare Accelerated and Advance Payment Program, and the provider relief payments distributed to hospitals served as a lifeline that provided fiscal stability during an unsettled time.

Issue

Although the relief payments were vital, not all costs were reimbursed. A number of hospitals have applied for Federal Emergency Management Agency support to fill the remaining fiscal voids. FEMA and the State Emergency Management Agency received applications for additional assistance dating back to 2021. Hospitals report that FEMA has designated many of the requests as "obligated," yet they remain unpaid. It is believed that the funds remain unpaid so that a FEMA contractor, the Homeland Security Operational Analysis Center and the Consolidated Resource Center can finish duplication of benefit reviews. HSOAC and the CRC communicated that the duplication of benefits reviews cannot take place for recent fiscal years due to the lack of publicly available data. SEMA also voiced concerns about releasing funds due to a fear that FEMA will disallow additional funding requests in the future. Hospitals are being held hostage from receiving funds due to a bureaucratic process that should be improved. Based on responses to a survey conducted by MHA, approximately \$400 million in FEMA/SEMA support has been requested and remains unpaid.

Request for Action

MHA urges Congress to compel FEMA to expeditiously process provider COVID-19 assistance applications and to instruct SEMA to, at the provider's request, release a portion of the requested support while duplication of benefit reviews continue.

Thank You: MHA thanks House Committee on Ways and Means Chairman Jason Smith (R-Mo.) for engaging FEMA to expedite application reviews.

ADVOCACY BRIEF

BLOCK MEDICAID DISPROPORTIONATE SHARE HOSPITAL FUNDING REDUCTIONS

Medicaid Disproportionate Share Hospital payments represent a critical reimbursement stream for hospitals — allowing them to capture the uncompensated costs of care provided to Medicaid beneficiaries and the uninsured. Medicaid DSH payments also provide necessary support to safety net hospitals. Medicaid DSH allotment calculations are state-specific and capped by statute. The amount a hospital can receive in Medicaid DSH payments also is limited by statute.

The Patient Protection and Affordable Care Act of 2010 called for significant cuts to Medicaid DSH payments beginning in 2014. Reductions were premised on the rationale that the coverage provisions of the ACA would reduce the number of uninsured individuals. As millions of Americans remained uninsured following passage of the ACA, Congress has delayed the reductions on several occasions. The Consolidated Appropriations Act of 2021 delayed them through federal fiscal year 2023. Currently, they are slated to take effect Oct. 1, 2024.

The Medicaid and Children's Health Insurance Program Payment and Access Commission is required to provide an annual report to Congress on the efficacy of the Medicaid DSH program. The report analyzes uncompensated care costs and the number of hospitals providing high levels of uncompensated care. In its March 2023 report, MACPAC expressed concern that implementation of the Medicaid DSH cuts could create immense financial stress on hospitals' operating margins, especially harming safety net hospitals. Among states, Missouri receives a fairly large Medicaid DSH allotment as a percentage of Medicaid spending, which partially is funded through the Federal Reimbursement Allowance that is paid by hospitals and significantly would be impacted by a reduction.

The total reduction in federally funded Medicaid DSH allotments is projected to be \$8 billion **per year** for FFYs 2024 – 2027. MACPAC estimates Missouri's share to be \$398.4 million in federal funds for 2024.

Many Missouri hospitals are financially stressed, especially those with high levels of uncompensated care. Those facilities particularly are vulnerable to the operational challenges posed by the COVID-19 pandemic and the nation's recovery therefrom, and they rely on Medicaid DSH payments to maintain financial viability, even at slim margins. Substantial reductions in Missouri's Medicaid DSH allotment could result in hospital closures, impeding access to care for many Missourians.

Request for Action

The Missouri Hospital Association urges the Missouri congressional delegation to enact legislation that would block implementation of the Medicaid DSH cuts slated to take effect Oct. 1, 2024.

MHA PROFILE OF MISSOURI HOSPITALS

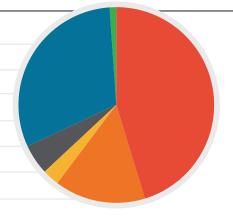
ALL HOSPITALS



- 66 Medicare acute Inpatient Prospective Payment System hospitals
- **35** critical access hospitals
- 5 federal military or veterans hospitals
- 5 general or specialty pediatric hospitals
- psychiatric hospitals
- long-term, acute care hospitals
- 6 rehabilitation hospitals
- for-profit organizations
- **109** tax-exempt organizations
- private, not-for-profit organizations
- 31 state or local government acute care hospitals
- psychiatric hospitals owned by the Department of Mental Health
- 3 free-standing children's hospitals

HOSPITAL PAYER MIX

- **45.3%** Medicare and Medicare Advantage
- **15.1%** Medicaid and Medicaid Managed Care
- **30.8%** Commercial and Managed Care
- **1.0%** Workers' Compensation
- **2.8%** Other Government
- **5.0%** Self-Pay



▶ 68.2% PERCENT OF BUSINESS REIMBURSING LESS THAN COST

1

OPERATING MARGIN

Percent of hospitals operating at a loss/gain.

30.2% `

69.8%

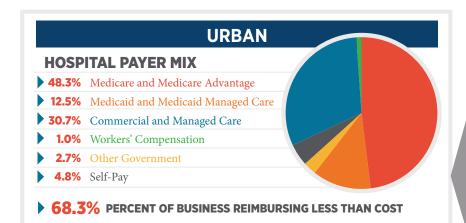


AVERAGE OPERATING MARGIN 2.7%

BUSINESS MIX

726,294 admissions **26,586,999** outpatient visits **36.6:1**

MHA PROFILE OF MISSOURI HOSPITALS



OPERATING MARGIN

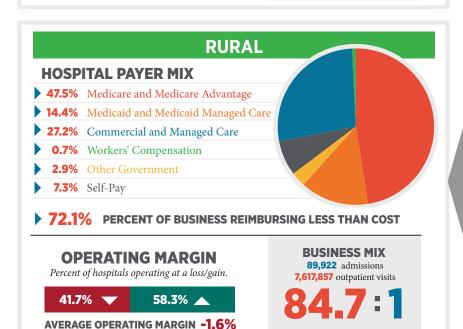
Percent of hospitals operating at a loss/gain.

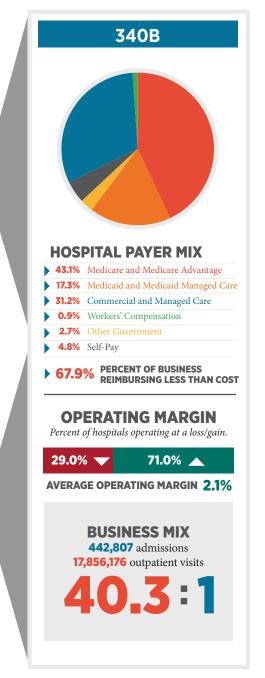
11.9%

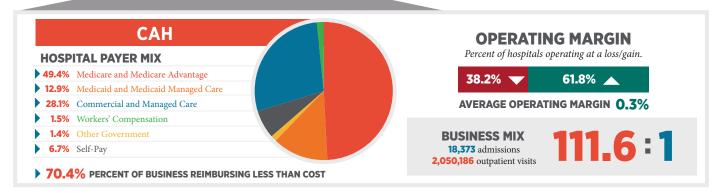
88.1%

AVERAGE OPERATING MARGIN 6.6%

BUSINESS MIX 589,433 admissions **17,371,152** outpatient visits







MHA

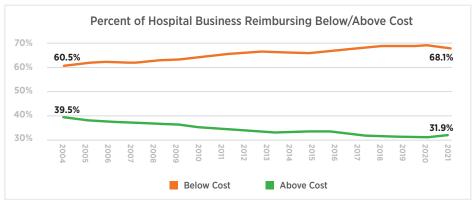
TRANSPARENCY IN HOSPITAL FINANCING

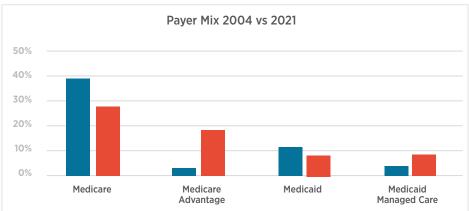


Shifting Payer Mix

Throughout the past 18 years, the percentage of business generated within Missouri hospitals has shifted from nongovernmental to governmental payment sources. This phenomenon will continue as the "silver tsunami" becomes Medicare enrollees. Governmental and self-pay business typically reimburse at less than cost that must be absorbed by nongovernmental business. Since 2004, the proportion of governmental and self-pay business has increased 12.6%, while the proportion of commercial and workers' compensation business has decreased 19.2%.

While the proportion of governmental business continues to increase, that business has shifted away from traditional coverage into Medicare Advantage and Medicaid managed care. This

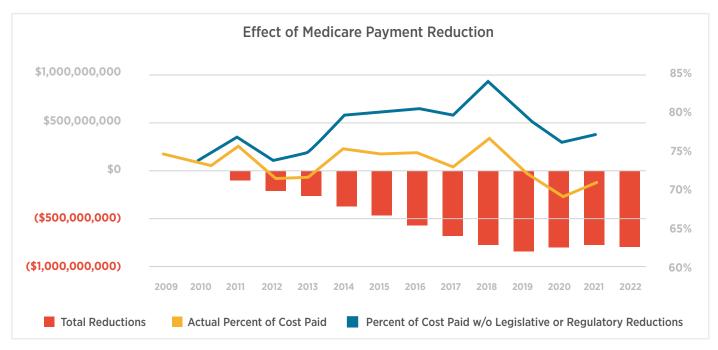




shift is causing significant problems for hospitals due to overly restrictive utilization management and prior authorization processes leading to coverage denials. These issues contribute to the amount of unreimbursed cost incurred from governmental payer sources.

Legislative and Regulatory Medicare Payment Reductions

Yearly Medicare payment rate increases are based on market basket updates established through regulation. Congress enacted laws that reduce the annual market basket update, and CMS further reduced Medicare payment rates through regulation. These actions are causing additional unreimbursed costs. Hospitals are required to absorb the Medicare reductions by contracting higher payment rates from a decreasing amount of commercial business. The legislative and regulatory Medicare payment reductions have exacerbated the shifting of cost absorbed by other payers.



Contrasting Percent of Cost Paid Between Medicare and Medicaid versus Commercial

Due to the shifting of payer mix and Medicare payment reductions, the need to shift cost has intensified. The financial voids created by Medicare, Medicare Advantage, Medicaid and Medicaid managed care are placing strains on commercial payment rates and premiums.

Cost-Shifting is Necessary to Sustain Hospital Margins

The unreimbursed cost incurred by serving governmental payer-sourced patients leads to cost-shifting onto insurers and enrollees. Due to the shifting of cost, the average annual premium for family coverage has increased 44% between 2013 to 2021.

Conclusion

Due to the increasing number of patients covered by a governmental insurance product, as well as the significant amount of cuts to Medicare reimbursement and amount of unreimbursed cost for services provided to governmental beneficiaries, cost-shifting has become necessary for hospitals to break

Missouri Hospital Percent of Cost Paid by Payer

140%

120%

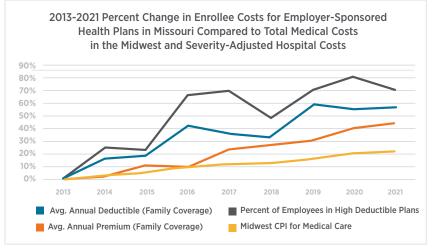
100%

80%

1997 1999 2001 2003 2015 2007 2009 2011 2013 2015 2017 2019 2021

Medicare and Medicare Advantage Percent of Cost Paid

Medicaid and Medicaid MCO Percent of Cost Paid



even or achieve a thin margin. This phenomenon is creating unintended consequences by placing more burden on nongovernmental enrollees.

The Missouri Hospital Association urges Congress to increase Medicare payment rates, hold governmental managed care companies accountable, and ensure that the CMS market basket updates are sufficient to prevent further cost-shifting and stabilize the hidden health care tax.

MEDICARE MARKET BASKET UPDATES FOR 2024

The Centers for Medicare & Medicaid Services provides annual Medicare prospective payment rate increases to ensure hospitals are appropriately compensated for care provided to Medicare beneficiaries. Medicare fee-for-service beneficiaries account for the largest volume of patients served within most Missouri hospitals. When Medicare payment rates lag behind inflation, the increased amount of uncompensated care cost can become untenable. The result produces an unsustainable fiscal condition that causes additional cost-shifting onto commercial beneficiaries.

Issue

In recent years, the Medicare market basket has fallen far short of inflation, which has caused negative Medicare margins nationwide. In its 2023 Report to Congress, MedPAC noted that "in 2021, Medicare's payments to hospitals continued to be below hospitals' costs in aggregate." Inpatient PPS "hospitals' Medicare margin increased in 2021 to -6.2% when including a share of federal relief funds (-8.3% exclusive of these funds)." "We project that hospitals' Medicare margins in 2023 will be lower than 2021, driven in part by growth in hospitals' input costs, which exceeded the forecasts CMS used to set Medicare payment rate updates." "The Commission anticipates that a fiscal year 2024 update to hospital payment rates of current law plus 1% generally would be adequate to maintain FFS beneficiaries' access to hospital inpatient and outpatient care."

CMS did not follow MedPAC's advice and released proposed 2024 market basket rate increases that fall well short of inflation. CMS' own data confirm the average hourly wage increase for federal fiscal year 2021 was more than 5%. CMS also included annual market basket index study results from FY 2019 through 2022 based on IHS Global Inc.'s forecasting model. For FY 2022, the increase was 5.3%. **Due to the rapid inflationary increase in 2022, prior years do not reflect the reality of today's cost to treat patients.** Although wages and the IGI forecast illustrate significant increases, CMS' proposed updates fall significantly short.

Fiscal Year	Proposed 2021-based Inpatient Psychiatric and Rehabilitation Market Basket Percent Change for FFY 2024	Proposed Acute IPPS Market Basket Percent Change for FFY 2024		
Historical Data				
FY 2019	2.4%			
FY 2020	2.1%			
FY 2021	2.8%			
FY 2022	5.3%			
Average 2019-2022 (proposed increase)	3.2% (actual is 3.0% after productivity adjustment)	3.0% (actual is 2.8% after productivity adjustment)		

1

Implications

Since the CMS market basket update has not kept up with recent inflationary pressures, Medicare PPS hospitals are more fiscally stressed than in the past. If CMS finalizes the market baskets as proposed, the stress will be even more prevalent. Already vulnerable hospitals will be at risk of closure.

Request for Action

The Missouri Hospital Association encourages members of Congress to support the Rural Hospital Support Act (S. 1110) introduced by Senator Robert Casey (D-Penn.) that would provide relief for Medicare-dependent, sole community and low-volume hospitals. MHA thanks Senator Josh Hawley for cosponsoring the legislation. While this would benefit a portion of the hospitals in Missouri if enacted, more needs to be done. MHA urges Congress to compel CMS to issue market basket increases that will keep pace with the recent increases in inflation.

2