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.

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.

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.

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, 2023.

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, 2023.

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 urges Congress to enact legislation to extend the following regulatory flexibilities that otherwise would become effective 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.

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.

WORKFORCE CHALLENGES

Hospitals are major employers within their communities, with staff comprised of highly paid professionals, technical experts and lower-wage positions across numerous disciplines. Each are necessary to ensure quality of care and a positive patient experience. Burnout, workplace violence and competitive pressures from other industries are creating untenable labor shortages in Missouri's hospitals that can threaten access to timely, convenient and appropriate care. The Missouri Hospital Association urges support of efforts to enhance the pipeline of health care workers, help hospitals create safe work environments and ease regulatory burdens that exacerbate workplace pressures.

Easing Labor Shortages

Issue: Turnover and vacancies are threatening Missouri hospitals' ability to maintain a strong, resilient workforce. According to MHA's Annual Workforce Report, turnover and vacancy rates among virtually every category of health professional reached an all-time high in 2021. Physician and nurse turnover and vacancy rates increase the reliance on contract labor. The American Hospital Association reports that contract labor costs increased 139% from 2019 to 2022, while the median wage rate paid to staffing agencies jumped 57%.

Rural hospitals especially are impacted due to difficulties recruiting personnel to nonurban locations. In fact, 2022 data from the Health Services and Resources Administration show nearly every Missouri county qualifies as both a primary care provider and mental health provider shortage area.

Action Taken: Missouri hospitals are employing creative staffing models that incorporate team-based care, as well as telemedicine and virtual care. Flexible scheduling, enhanced workplace support systems and wellness programs coupled with financial incentives are being used to recruit, retain and create resilient employees. Hospitals commonly partner with nursing education programs to provide clinical training sites and fund clinical faculty.

Request for Action

Legislation is needed to increase the number of employed doctors and nurses to reduce anticompetitive action by staffing agencies. Congress could support these efforts in the following ways.

- Support of the bipartisan Resident Physician Shortage Reduction Act of 2023 (H.R. 2389) introduced by Representatives Terri Sewell (D-Ala.) and Brian Fitzpatrick (R-Pa.) that would increase the number of Medicare-supported medical residency positions by 14,000 over a seven-year period.
- Support of the Conrad State 30 and Physician Access Reauthorization Act (S. 665) introduced by Senator Amy Klobuchar (D-Minn.) that would extend the

Conrad 30 program for three years, improve the process for obtaining a visa and allow for the program to be expanded beyond 30 slots if certain thresholds are met.

» Support of H.R. 2411 introduced by Representative Lisa Blunt Rochester (D-Del.) and S. 1150 introduced by Senator Jeff Merkley (D-Ore.) that amends the Public Health Service Act to support and stabilize the existing nursing workforce and establishes programs to increase the number of nurses.

» Urge the Federal Trade Commission and U.S. Department of Justice to investigate and stop price gouging by health care staffing agencies

Thank You: MHA thanks the 117th Congress for adding 1,000 Medicare-funded physician residency slots.

Enabling Safe Work Environments

Issue: Workplace violence continues to plague health care. Patients and visitors, thrust into stressful situations surrounding their own or a loved one's health, often lash out at providers. Patients suffering from acute behavioral health episodes or substance use disorders may aggressively resist treatment. Domestic violence also can follow staff into the hospital. Since the beginning of the COVID-19 pandemic, violence against hospital employees has increased. According to the Bureau of Labor Statistics, the rate of injuries from violent attacks against medical professionals increased 63% from 2011 to 2018. The American Hospital Association reports that during the COVID-19 pandemic, 44% of nurses were victims of physical violence and 68% were subjected to verbal abuse. Violence in the health care setting threatens not only the health and safety of hospital staff but affects their ability to care for patients.

Action Taken: Federal and state laws mandate that hospitals continually scan and evaluate their environment for vulnerabilities and threats. Employees are trained to recognize and deescalate aggressive behavior. Hospitals frequently partner with local law enforcement agencies to deter and mitigate unlawful or violent incidents on hospital premises.

Request for Action

MHA supports legislative proposals that protect health care workers while ensuring a safe environment for patients and their families. MHA applauds resolutions such as H. Res. 27 introduced by Representative Diana DeGette (D-Colo.) that condemns attacks on health care facilities, health care personnel and patients. MHA appreciates Representatives Cori Bush (D-Mo.) and Emanuel Cleaver (D-Mo.) for cosponsoring the resolution. MHA urges Congress to enact legislation that would provide funding for projects to enhance safety within hospitals.

Minimum Staffing Ratios

Issue: Health care leaders throughout the country cite the workforce crisis as one of the top operational issues facing institutional providers. Within Missouri, obtaining additional nurses is difficult to nearly impossible. While applications to registered nursing programs remain strong, nursing schools do not have sufficient faculty or training sites to accommodate additional students. The Missouri State Board of Nursing 2020 Annual Report indicates that of the 90 Missouri prelicensure nursing programs, at least 45 have unfilled full-time and 44 have open part-time adjunct nurse faculty positions. The absence of nurse faculty positions results in fewer nurses being introduced into the health care workforce pipeline.

The strain on the health care workforce throughout the nation should be considered by Congress and the Centers for Medicare & Medicaid Services when assessing whether to implement minimum staffing requirements. Implementing minimum staffing requirements could lead to an exacerbation of the staffing shortage that exists for all provider settings. Additional implications include less access to long-term care beds, more cost to treat patients and reduced innovation. Minimum nurse staffing ratios will not result in improved quality, increased safety or reduced cost.

Request for Action

MHA urges Congress to block CMS from implementing minimum staffing requirements. MHA also urges Congress to not support or enact H.R. 2530 introduced by Representative Janice Schakowsky (D-Ill.) or S. 1113 introduced by Senator Sherrod Brown (D-Ohio). Both proposals would establish direct care RN-to-patient staffing ratio requirements in hospitals.