PROTECT THE 340B DRUG DISCOUNT PROGRAM

Missouri's hospitals and others oppose the recent efforts of pharmaceutical manufacturers to limit the breadth of the 340B drug discount program.

A number of pharmaceutical manufacturers have instigated diverse but well-choreographed efforts to upend long-standing 340B practices. Some rely on onerous new demands for data and documentation couched as criteria for payment. Others arbitrarily declare that drug discounts no longer will be provided through contract pharmacies, brazenly attempting to negate by fiat a well-established component of the 340B program.

By unilaterally creating new obstacles to the use of 340B drug discounts to benefit low-income patients, the pharmaceutical manufacturers trim their financial obligations. The "cost" of the 340B program is borne by pharmaceutical manufacturers, not the federal treasury.

We believe their efforts are illicit and unjustified.

The pharmaceutical company forays take different approaches, but they all run counter to both the letter and spirit of the 340B law. In the attached letter, MHA and the Missouri Primary Care Association ask the U.S. Department of Health and Human Services to use its regulatory authority to block them. If the agency fails to do so, Missouri's 340B hospitals urge Congress to step in to protect the integrity and intent of the 340B law.

- Enacted in 1992 and last expanded in 2010, the 340B law requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to safety-net providers, including community health centers and various types of hospitals.

- 66 of Missouri's 140 hospitals participate in the 340B program, distributed as follows in the congressional districts:
  - Clay – 6
  - Wagner – 2
  - Luetkemeyer – 4
  - Hartzler – 9
  - Cleaver – 5
  - Graves – 15
  - Long – 10
  - Smith – 15

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Missouri Primary Care Association

September 4, 2020

Thomas Engels, Administrator
Health Resources and Services Administration
5600 Fischers Lane
Rockville, MD 20857

Dear Administrator Engels:

You are aware of concerns and objections regarding the efforts of a number of pharmaceutical manufacturers to limit the breadth of the 340B drug discount program. The Missouri Hospital Association and the Missouri Primary Health Care Association resoundingly reiterate those concerns and objections. The diverse but well-choreographed efforts by these pharmaceutical manufacturers upend long-standing 340B practices in order to trim their financial obligations. We believe those efforts are illicit and unjustified. We ask your agency to act quickly and decisively to block them and maintain the integrity and intent of the 340B program.

These pharmaceutical manufacturers are unilaterally creating new obstacles to the use of 340B drug discounts to benefit low-income patients. Some rely on onerous new demands for data and documentation couched as criteria for payment. Others arbitrarily declare that drug discounts will no longer be provided through contract pharmacies, brazenly attempting to negate by fiat a well-established component of the 340B program.

These pharmaceutical company forays take different approaches, but they all run counter to both the letter and spirit of the 340B law. There have been questions raised over the years about the parameters of HRSA's regulatory authority over 340B. After debating expansions of that authority, key Congress committees have urged HRSA to make full use of the regulatory authority it already has. To that end, our organizations implore HRSA to do what it can and must do to stifle these attempts to undermine the 340B program. Low-income patients are being deprived of the benefit of 340B drug discounts to which they and the qualified safety net providers who serve them are entitled by law and long-standing practice.

On September 3, the chairpersons of the House of Representatives Energy and Commerce Committee and its subcommittees on Health and Oversight and Investigations wrote Secretary Azar regarding this matter. We concur with the sentiments expressed as to HRSA's capacity and responsibility to act.

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HHS has an obligation to ensure manufacturers comply with the law. Furthermore, Congress has provided you with tools, including manufacturer auditing rights and civil monetary penalties, to enforce it. Failure to enforce 340B requirements threatens to undermine program integrity. Allowing manufacturers to institute extralegal requirements on covered entities under the threat of refusing to ship drugs as required, or allowing manufacturers to pick and choose where they will comply with program requirements, could set us on a treacherous path where program participants might disregard any or all of their legal obligations.

Thank you for your consideration of this vitally important matter.

Sincerely,

Herb B. Kuhn
President and CEO
Missouri Hospital Association

Joe Pierle
President and CEO
Missouri Primary Care Association

Hk:Jp/drd

COVID-19 (CARES ACT) FUNDING

Missouri's hospitals urge Congress to add $100 billion to the Public Health and Social Services Emergency Fund to support health care providers in the ongoing COVID-19 pandemic. While some of the funds already allocated for that purpose remain unspent, the need for financial assistance continues.

The Missouri Hospital Association's analysis indicates that the federal COVID-19 financial relief provided to Missouri hospitals, while substantial and deeply appreciated, will offset a modest portion of their cumulative financial losses by the end of 2020, as described in the attached infographic. National studies show similar results.

Hospitals in Missouri have received an average of 4.8 percent of their annual operating revenue in relief funding. Based on an April survey, it is estimated that annual operating revenues will be 25.2 percent below last year. MHA is updating this projection based on September survey results. Preliminary results indicate that the reductions in operating revenue will not be as severe as originally projected. While this is promising and the operating revenue is beginning to return, further federal funding relief is needed to offset the pandemic-related losses incurred by Missouri hospitals.

The U.S. Department of Health and Human Services will continue to dole out funds as needed to respond to emerging conditions. However, there needs to be a ready reserve available to address conditions that may emerge if the resurgence of the virus continues and is exacerbated by a challenging influenza season this fall and winter.

The attached infographic shows the role of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) funding for Missouri hospitals. Note that one-third of the financial assistance has been in the form of grants. Two-thirds of the total involves loans with repayment obligations.

THE FINANCIAL TOLL OF COVID-19 ON MISSOURI HOSPITALS

The pandemic threatens the viability of Missouri hospitals and their communities.

NATIONAL PROJECTIONS

↓ 19.5% INPATIENT SERVICES

↓ 34.5% OUTPATIENT SERVICES

Nationally, volume is projected to decrease from baseline by 19.5% for inpatient services and 34.5% for outpatient services.

Projected losses for the aggregated national group of hospitals in 2020

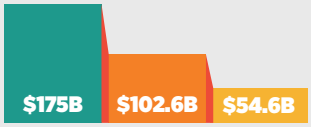
$323.1B

- **$202.6B** MARCH - JUNE
- **$120.5B** JULY - DECEMBER

$3.8B

Nationally, the cost to acquire PPE from July – December

Public Health and Social Services Emergency Fund Allocation



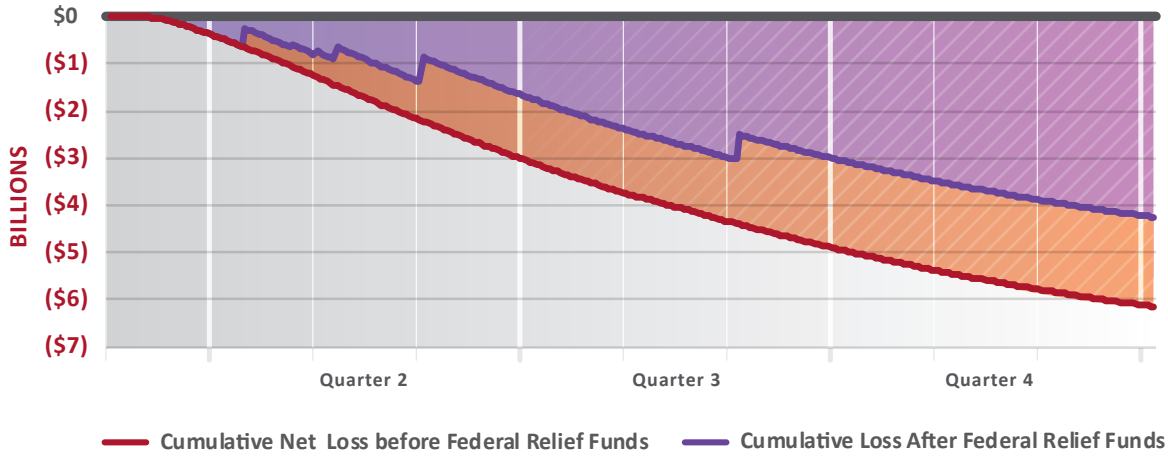
PHSSEF | PHSSEF paid to all providers | PHSSEF paid to hospitals

Source: AHA report: Hospital financial losses from COVID-19 expected to top $323 billion in 2020

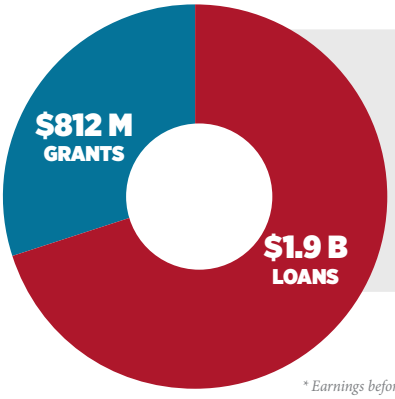
MISSOURI PANDEMIC EFFECTS

FEDERAL RELIEF HELPS BUT CANNOT KEEP UP WITH REVENUE LOSSES

*The chart below illustrates the effect of projected revenue reductions of an average of **$29.1M per day** during Quarter 2, **$20.7M per day** during Quarter 3 and **$13.2M per day** during Quarter 4, as well as projects the impact of the CARES Act funding relief.*



MISSOURI MOVING FORWARD



The CARES Act is bringing much needed funding to hospitals. In total, hospitals have received **$2.7 billion** in relief funding. However, **70%,** or **$1.9 billion,** are considered loans that hospitals are required to pay back.

EBIDA* w/o CARES Act Funding Relief	EBIDA* w/ CARES Act Funding Relief
-$3.97 B	**-$2.07 B**

** Earnings before interest, depreciation and amortization, and is based on annual licensing survey data, hospital survey results, and extrapolations performed by MHA.*
Grants vs. Loans Source: U.S. Department of Health and Human Services, hospital survey results, and extrapolations performed by MHA.

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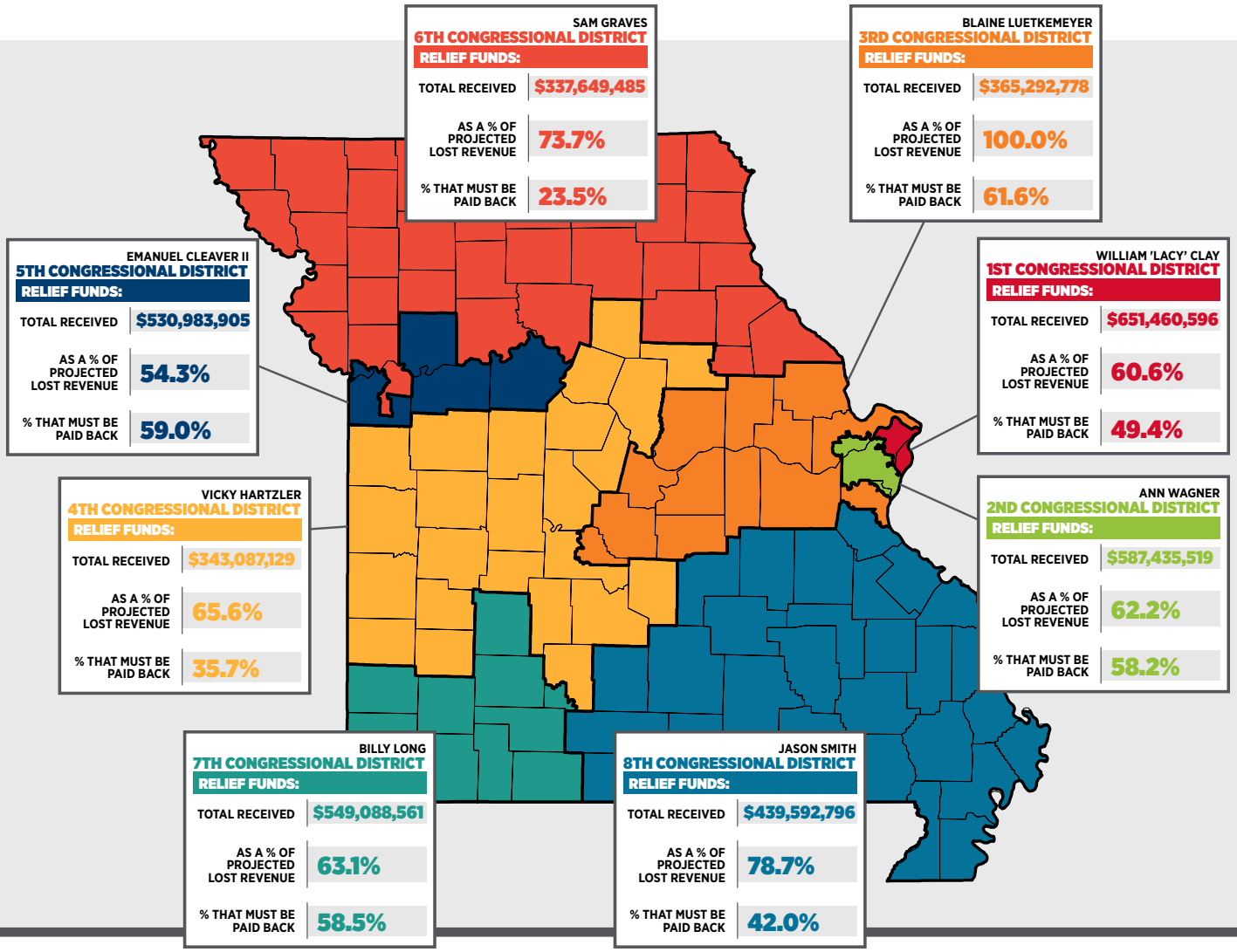
REVENUE REDUCTIONS

DISTRICT	REPRESENTATIVES	Q2 REVENUE REDUCTION PER DAY	Q3 REVENUE REDUCTION PER DAY	Q4 REVENUE REDUCTION PER DAY	Q2 - Q4 REVENUE REDUCTIONS TOTAL
1	Clay, William 'Lacy'	$5,477,399	$3,786,309	$2,475,171	$1,074,499,584
2	Wagner, Ann	$4,760,485	$3,395,800	$2,159,802	$944,319,566
3	Luetkemeyer, Blaine	$1,827,544	$1,330,249	$831,322	$365,171,032
4	Hartzler, Vicky	$2,636,176	$1,880,853	$1,196,048	$522,966,968
5	Cleaver II, Emanuel	$4,986,869	$3,435,356	$2,252,536	$977,091,103
6	Graves, Sam	$2,290,958	$1,669,623	$1,042,291	$457,973,220
7	Long, Billy	$4,365,316	$3,151,671	$1,983,606	$869,689,245
8	Smith, Jason	$2,797,598	$2,029,029	$1,271,987	$558,274,859
	TOTAL	$29,142,345	$20,678,892	$13,212,762	$5,769,985,578

Projected Volume Reductions From Prior Year

	Change in Inpatient Admissions			Change in Outpatient Visits		
	Quarter 2	Quarter 3	Quarter 4	Quarter 2	Quarter 3	Quarter 4
TOTAL	35%	20%	16%	56%	44%	26%

The percentages of revenue reduction offset by relief funding and the percentages of relief funding that are loans to be repaid vary substantially between congressional districts. They are interrelated.



REPAYMENT TERMS FOR ACCELERATED PAYMENTS

In the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Congress expanded the Medicare Accelerated Payment program. It provided a means for many Missouri hospitals to survive the combined loss of elective procedures and increased COVID-19 pandemic expenses, while the financial relief authorized elsewhere in the act could be designed and implemented. The accelerated payment program allowed hospitals to receive an advance payment based on their Medicare fee-for-service billings, with recoupment of the advance from future Medicare payments. Essentially, this served as a short-term loan. CMS made the accelerated payments available from April 1 to April 26, when applications for funding were suspended.

The CARES Act directs that recoupment of the accelerated payments begins 120 days after its receipt, so all participating Missouri hospitals now are subject to having all of their Medicare fee-for-service claims payments withheld to offset the debt. If the entirety of the debt obligation is not repaid within 12 months through the withholding of Medicare payments, the hospital must pay the balance directly or incur interest at a rate exceeding 10%.

On average, Medicare fee-for-service payments comprise about 48% of rural hospital revenues, so the current loss of Medicare payments is a daunting cash-flow challenge. The problem is exacerbated by the ongoing demands of the COVID-19 pandemic. While some of the elective procedures have returned at many hospitals, hospital finances are far from pre-COVID-19 levels of sustainability. Missouri Hospital Association projections indicate the federal financial relief provided from March through December of 2020 will offset approximately one-third of Missouri hospitals' cumulative financial losses arising from the pandemic by the end of the year. Also, it is important to note that of the $2.7 billion in federal relief funding received by Missouri hospitals from the CARES Act — 70% or $1.9 billion — are loans that must be repaid.

To that end, Missouri's hospitals urge the Missouri congressional delegation to support legislation to relax the repayment obligations of the Medicare Accelerated Payment program. Several options could be made available based on a hospital's financial situation.

- Repayment obligations could be deferred.
- Repayment obligations could be extended over a longer period of time.
- Repayment obligations could be forgiven.
- The percentage of current Medicare claims payments withheld to offset the debt could be lowered from 100%.
- Congressman Jason Smith's legislation, H.R. 7759, authorizes CMS to forgive, delay or reduce the interest rate for repayment obligations for Medicare Accelerated Payments based on a showing of financial hardship. It is co-sponsored by three other members of the Missouri congressional delegation.

Missouri's hospitals also urge Congress to significantly lower the interest rate of more than 10% charged for unpaid balances 12 months after loan issuance.

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DELAY OF PENDING MEDICAID DSH PAYMENT CUTS

Current federal law calls for significant reductions in states' Medicaid Disproportionate Share Hospital allotments. The allotments are the state-specific amounts of federal matching funds for Medicaid DSH payments. Unless Congress affirmatively acts, the statutory reductions will take effect December 1. The implementation date was last delayed by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Previously, Congress enacted delays in 2013, 2014, 2015 and 2018.

The total reduction in Medicaid DSH allotments is $4 billion dollars for fiscal year 2021. While the details of how CMS will distribute the payment loss among the states are uncertain, past regulations suggest that Missouri stands to lose $146 million. The following fiscal year, the national reduction in Medicaid DSH funding doubles to $8 billion. Missouri's share likely would be more than $300 million in FY 2022.

In Missouri, Medicaid DSH payments offset part of hospitals' cost of treating the uninsured. The state share of DSH payments is funded solely by the state hospital provider tax.

Originally imposed by the Affordable Care and Patient Protection Act of 2010, the Medicaid DSH allotment reductions were to begin in 2014 in conjunction with expanded coverage. The premise underlying them is that the Affordable Care Act would expand coverage and reduce the number of uninsured Americans, eliminating some of the need for federal Medicaid DSH payments to offset hospitals' uninsured costs. Instead, the money could be used to offset some of the cost of expanded coverage. When the U.S. Supreme Court struck down the ACA's mandate for states to expand eligibility for their Medicaid programs, Missouri was one of the states that opted to reject the expansion. Hospitals in Missouri and other nonexpansion states are facing big Medicaid DSH payment cuts with no offsetting coverage benefit. While Missouri voters authorized Medicaid expansion in August, its implementation is scheduled for July 1, 2021, at the earliest.

Missouri has a relatively large Medicaid DSH allotment, and its distribution system directs Medicaid DSH payments to many hospitals. The scheduled cuts, therefore, are particularly ominous for Missouri.

MHA urges the Missouri congressional delegation to take action to block or delay these Medicaid DSH reductions. Nothing has occurred to make the DSH allotment reductions more justifiable in December 2020 than they were when Congress enacted its previous delays.

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CONTINUATION OF EXPANDED TELEMEDICINE USE

In response to the COVID-19 pandemic, approximately 500 waivers of federal and state regulatory and statutory standards were issued to relieve administrative burden and promote continued access to care. Missouri's hospitals deeply appreciate the flexibility enabled by these waivers.

Some of those waivers provided strong evidence of better ways to deliver health care. For example, the waivers enabled a significant expansion of the use of telemedicine.

A July 28 federal analysis of telemedicine use in the Medicare program found the following.

- Medicare fee-for-service in-person visits for primary care fell precipitously in mid-March at the start of the COVID-19 public health emergency and began to rise again in mid-April through May.
- Nearly half (43.5%) of Medicare primary care visits nationally were provided via telehealth in April, compared with less than 1% before the PHE in February (0.1%).
- In Missouri, the percentage of Medicare primary care visits provided via telehealth was less than 0.05% in February and 35.4% in April.
- As in-person visits started to resume from mid-April thru May, the use of telehealth in primary care declined somewhat but appears to have leveled off at a persistent and significant level by the beginning of June.

The analysis by the Office of the Assistant Secretary for Planning and Evaluation in the U.S. Department of Health and Human Services concludes that "there is evidence that Medicare's new telehealth flexibilities played a critical role in helping to maintain access to primary health care services — when many beneficiaries and providers were concerned with transmission of COVID-19. The stable and sustained use of telehealth after in-person primary care visits started to resume in mid-April suggests there may be continued demand for telehealth in Medicare, even after the pandemic ends." The agency's findings are borne out; there is strong provider and patient support for the expanded use of telemedicine.

A survey of the Missouri Hospital Association membership found that 90% of the Missouri hospitals implementing federal or state regulatory waivers in response to COVID-19 did so to expand telemedicine capacity.

MHA and its members encourage the Missouri congressional delegation to support legislative proposals to convert telemedicine waiver authorities to permanent policy.

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COVID-19 LIABILITY PROTECTION

Missouri's hospitals urge Congress to enact federal liability protections for actions taken by hospitals and other health care providers to deliver and manage health care services during a federally declared public health emergency.

Some states have enabled this type of liability protection through legislative enactments or executive orders. The Missouri General Assembly did not act on this topic in its interrupted regular session in 2020 and the governor's authority to act via executive order is unclear. If state legislative action is delayed until 2021, a new law likely will not become effective until August 28, 2021.

Also, federal action can establish uniform standards, limiting the incentive for practitioners to relocate to more favorable states.

Congressional action is needed.

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