National Organization of
State Offices of Rural Health

July 27, 2023

NOSORH Comments on Senate 340 B Drug Discount Program Request for Information (RFI)

Introduction

On June 16, 2023, a bipartisan group of United States Senators released a letter to stakeholders on issues related to the 340 B Drug Discount Program. The letter reflected concerns about whether the Program is effectively meeting its purposes and whether it is sufficiently accountable in its operations. The letter includes a request for Information (RFI) with specific questions about the program's operations and accountability. The RFI seeks comment on these matters and solicits recommendations on how the Program might be improved.

In this communication, the National Organization of State Offices of Rural Health (NOSORH) provides its input in response to the RFI. NOSORH's comments highlight the significant role of the 340 B Drug Discount Program in helping to sustain the nation's rural health services system. The comments provide perspective on the multiple ways in which the savings afforded by the Program are used by participating rural health service providers to meet the needs of patients in their communities. The comments also provide specific comments on how monitoring and accountability of the 340 B Discount Program might be improved. NOSORH believes that improved accountability will better document the success of the Program.

NOSORH was established in 1995 to assist State Offices of Rural Health (SORHs) in their efforts to improve access to, and the quality of, health care for over 60 million rural Americans. All 50 states have a SORH, and each SORH helps their state's rural communities to build effective health care delivery systems. NOSORH and its members work closely with rural health care providers nationwide, including Rural Health Clinics, Federally Qualified Health Centers, and rural hospitals. NOSORH brings its knowledge of rural essential community providers to the concerns of this RFI.

NOSORH is encouraged that the Senate is exploring issues related to the 340 B Drug Discount Program. NOSORH believes that the Program has received unwarranted criticism of its performance, largely due to a narrow view of its actual effectiveness. NOSORH also believes that appropriate monitoring and accountability detailing *all* the impacts of the Program can easily justify its continuation.

Overview – Use of 340 B Drug Discount Program Net Savings

NOSORH understands that multiple groups have expressed concerns about the *use of the net savings* from 340 B discounts. Several reports issued by 340 B Health, the association of 340 B Program participating hospitals, have addressed these concerns, documenting that participating hospitals are using savings to provide more services to low-income patients and enhance patient treatment services. As an example, see a recent summary analysis here:

- https://www.340bhealth.org/files/340B_Health_Survey_Report_2021_FINAL.pdf

NOSORH believes that these studies accurately reflect how the 340 B Program is operating in rural hospitals as well as other rural health service providers.

In these comments NOSORH will describe how the 340 B Drug Discount Program savings are used by rural health service providers for three important purposes:

- To ***sustain operations*** of low-volume rural health services,
- To provide ***support for under-reimbursed health services****, and*
- To provide ***support for uncompensated care***.

NOSORH will also provide comment on how contract pharmacies participating in the 340 B Drug Discount Program improve the accessibility of pharmacy services in rural communities and help to contain the costs of providing health care. Finally, NOSORH will provide comment on how 340 B Drug Discount Program monitoring and accountability could be improved.

Issue: Benefits of 340 B Drug Discount Program

NOSORH believes that the net savings associated with the 340 B Drug Discount Program are appropriately used by participating rural health service providers for the purposes described below.

Sustaining low-volume rural health services: The 340 B Program contributes significantly in rural communities to ***the maintenance of essential services that would otherwise be unsustainable***. NOSORH considers this to be the main benefit of the Program. Health care providers in many rural communities operate in a low-volume environment when compared to providers in urban communities. The lower volume of demand for key essential services makes it difficult to sustain these services based entirely on generated revenue. Nevertheless, for example, few would argue that Emergency Medical Services should not be available in rural communities, even if the generated revenue from these services does not offset their cost. Standby capacity is needed to assure that these services can be provided. The cost of this needed infrastructure can be significant. Other sources of funding are needed to assure that these services can be maintained.

The sustainability of rural health care providers – and rural hospitals – has emerged as a major national concern. Hundreds of rural hospitals have closed their doors in the last few years. This problem has been well documented:

- https://www.ruralhealthresearch.org/assets/5299-24183/hospital-closures-2023-recap.pdf

Despite Federal, state, and local efforts, this problem is likely to continue, and will likely accelerate. As many as 600 rural hospitals may be at risk of closing:

- https://www.usnews.com/news/health-news/articles/2023-01-16/hundreds-of-hospitals-could-close-across-rural-america
- https://guidehouse.com/-/media/www/site/insights/healthcare/2020/guidehouse-navigant-2020-rural-analysis.ashx

340 B Drug Discount Program savings are an important part of supplemental funding need to maintain essential rural health services. Any reduction of 340 B Program savings to rural providers could compound problems of financial sustainability.

It is not just the *overall operations* of rural health service providers that face sustainability challenges. In rural communities the net savings of the 340 B Program is a major source of funding needed to maintain *specific essential services* that are not economically viable. These services include:

- Maternity and delivery services,
- Emergency medical services and emergency room services,
- Prevention and community health improvement services, and
- Translation and other patient support services.

Without 340 B Program savings many of these essential services could be cut back or eliminated.

Maternity and obstetric care services in rural communities are another major national concern. The availability of these services has eroded in the last few years:

- https://www.cnn.com/2023/04/07/health/maternity-units-closing/index.html
- https://www.axios.com/2023/01/17/hospital-obstetrics-chopping-block

There are multiple causes of this service contraction, not the least of which is inadequate reimbursement under Medicaid programs, a major source of maternity coverage nationwide. 340 B Program savings help offset the unreimbursed costs of care for obstetric and maternity services.

Support for under-reimbursed services: NOSORH understands that there are many instances where 340 B Drug Discount Program savings help offset the losses of *under-reimbursement*. A case in point is that of Federally Qualified Health Centers (FQHCs). FQHCs receive reimbursement for their Medicaid patients based upon PPS rates negotiated with state Medicaid programs. These rates are set at a level which is typically about 80% of the actual cost of service. Federal grants to FQHCs can help defray some of these losses, but 340 B Program savings and other funding is needed to sustain FQHC services for their Medicaid patients.

Support for uncompensated care: All rural health care providers face a challenge related to the need for *uncompensated* care. This can include the cost of care provided to uninsured and indigent individuals. It can also include the cost of care for insured individuals who are unable to pay their co-pays or deductibles. With the significant increases in cost-sharing required by many health plans, this second category of uncompensated care is becoming more significant.

340 B Drug Discount Program savings is an important source of funding used to offset the cost of uncompensated care. NOSORH notes that this may not be the primary use of these Program savings for participating rural health providers. The costs of sustaining basic operations can easily outweigh the cost of uncompensated care.

NOSORH also notes that the end of the COVID-19 Public Health Emergency (PHE) is having a significant impact on rural health service provider uncompensated care. During the PHE, individuals who qualified for Medicaid were able to maintain that eligibility throughout the period of the PHE without a need for supplemental eligibility review. This expanded the number of Medicaid enrollees. The 'unwinding' of this continuing enrollment is expected to increase the number of uninsured individuals nationwide by over 10 million, with some states increasing their uninsured populations

disproportionately. Rural health service providers will need to shoulder an increased level of uncompensated care:

- https://coloradonewsline.com/2023/02/21/rural-hospitals-unwinding-pandemic-medicaid-coverage/

- https://www.mdlinx.com/news/federal-medicaid-unwinding-could-cause-community-health-centers-to-lose-care-capacity-for-as-many-as/6K9PnG0Iw4EN7uiyFNkS3o

340 B Program savings will help in offsetting this increased financial burden. This is discussed in more detail in the next section of these comments.

Impact of COVID-19 Pandemic: NOSORH notes that the COVID-19 PHE has had a mixed impact on the sustainability of rural health services. While the pandemic itself was associated with higher operating costs and reduced generated revenue, other funding sources emerged. During the PHE, many rural health providers received temporary financial support from programs like the Provider Relief Fund. They also received some assistance from temporary flexibilities on the reimbursement of telehealth services as well as extensions of Medicaid coverage to those individuals affected by the pandemic. Finally, they received subsidies to be used specifically for the testing and treatment of the COVID-19 virus.

The end of the PHE and the initiation of Medicaid continuing coverage unwinding will end these temporary subsidies. The termination of the PHE will make 340 B Drug Discount Program savings that much more important for rural health care providers.

Recommendation: NOSORH strongly suggests that any evaluation of the effectiveness of the 340 B Drug Discount Program ***include all appropriate uses of the net savings of the Program***. NOSORH believes that much of the criticism of the Program has considered a single potential use of the net savings – offset of uncompensated care. NOSORH believes that the actual use of net savings, particularly by participating rural health service providers, includes multiple other appropriate purposes. These other uses must be considered in an accurate assessment of the Program.

Issue: 340 B Drug Discount Program Contract Pharmacies

Rural pharmacies are a vital component of the rural health services system. They provide a local source of pharmaceutical, health supply, health equipment and health education services that might otherwise require lengthy travel. Pharmacies serve the entire rural community, including the patients of 340 B Drug Discount Program participating providers. In serving this larger population rural pharmacies often maintain formularies and inventories more extensive than those of individual participating 340 B Program providers.

During the COVID-19 Public Health Emergency rural pharmacies played a vital role. They were a major service point for administration of immunizations and for dispensing treatment medications. They were also a source of testing supplies, including tests subsidized by public programs.

There are growing challenges to the sustainability of rural pharmacies. Closures of rural pharmacies have increased:

- https://dailyyonder.com/rural-communities-lose-10-of-their-pharmacies-in-the-last-two-decades/2022/09/13/

This has resulted in an increase in the number of *pharmacy deserts* – communities without accessible pharmacies – both in rural and urban areas.

- https://rupri.public-health.uiowa.edu/publications/policybriefs/2022/Pharmacy%20Deserts.pdf

- https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/

If pharmacy services are not accessible, patients will delay or forego needed treatment. This will result in poorer health outcomes and increased overall health service costs.

340 B Program participating providers use contract pharmacies for multiple reasons. Contracted pharmacies can dispense medications at a cost lower than might be incurred if 340 B Program participants provided them directly. This is often the case, even after factoring in the contracted cost of dispensing.

Use of contract pharmacies reduces the need for health service providers participating in the 340 B Program to maintain an extensive pharmacy inventory. The use of contract pharmacies can also reduce participating provider staffing costs. These cost savings are particularly important for rural FQHCs. Besides the savings associated with reduced formulary inventories, FQHCs using contract pharmacies can secure substantial staffing savings. This includes the savings associated with the need to maintain the costly services of a supervising pharmacist.

The additional volume of dispensing at 340 B contract pharmacies contributes to the likelihood of pharmacy sustainability. This can help prevent closures and can reduce the increase in pharmacy deserts. This is an important consideration in the preservation of the rural health services system.

Recommendation: NOSORH strongly supports the continuation of guidance that permits the use of contract pharmacies by 340 B Program participants. The use of these pharmacies, including independent, chain and franchise pharmacies, is advantageous to patients and to the health care system – particularly in rural communities.

NOSORH also condemns restrictions imposed on the use of 340 B Program contract pharmacies by certain pharmaceutical companies. NOSORH urges Federal action to end these inappropriate restrictions.

Issue: Accountability for the Use of 340 B Drug Discount Program Savings

NOSORH believes that, overall, the use of 340 B savings is appropriate and meets the purposes of the original authorization. At the same time, NOSORH feels that improved monitoring and accountability of the use of those savings could better document the success of the Program.

NOSORH feels that an annual report of 340 B Drug Discount Program savings should be submitted by all health service providers participating in the Program. NOSORH believes that the report should cover all appropriate uses these savings, including the use of savings for:

- Maintaining the overall sustainability of participating health provider operations;

- Maintaining the operation of essential specific health provider lines of service, such as obstetric services;
- Offsetting losses due to under-compensated health care service delivery; and
- Offsetting losses due to uncompensated health care delivery.

NOSORH believes that this monitoring and accountability can be accomplished in a manner which does not place an unnecessary burden on participating 340 B Drug Discount Program providers. As an example, Schedule H of the IRS 990 form, covering community benefit of 501 (c) (3) nonprofit hospitals, could be used as a model. In this report, hospitals identify a range of different community benefit activities and the expenditures associated with them. A similar approach could be used for an annual summary of the uses of 340 B Drug Discount Program savings.

Recommendation: NOSORH recommends that the Health Resources and Services Administration consult with representatives of health service providers participating in the 340 B Drug Discount Program to develop an appropriate annual report detailing the use of net Program savings. NOSORH suggests that representatives of *all* categories of eligible health service providers be consulted in this process, with the aim of improving Program accountability without creating overly burdensome requirements for any class of health service provider.

Issue: Standards for Use of 340 B Drug Discount Program Savings

There have been discussions about establishing minimum standards for the use of 340 B Drug Discount Program savings. For example, it has been suggested that a standard percentage of these savings should be targeted for use in offsetting the cost of uncompensated care. NOSORH does not believe that setting specific standards for the use of 340 B Drug Discount Program savings would be useful. NOSORH feels that no single standard could appropriately apply to the different categories of participating 340 B Program health service providers. The operations of Disproportionate Share Hospitals, FQHC-lookalikes, Sexually Transmitted Disease Clinics, Title X Family Planning Clinics and Critical Access Hospitals are very different. Some operate with a required sliding fee discount schedule, and these adjustments are accounted for separately from uncompensated care amounts. Other service providers operate in the Public Health arena, and do not charge for services. A single operational standard on the use of 340 B Program savings for uncompensated care would not work for all categories of service provider. Other types of specific standards would also likely fail in their application to the range of eligible health service providers.

Recommendation: NOSORH recommends against the use of ***specific*** standards for the use of 340 B Drug Discount program savings. NOSORH feels that ***general*** standards could be established, assuring that net savings are being used, in accordance with the authorizing statute, to "*stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services*". NOSORH believes that improved monitoring and accountability can assure that the 340 B Drug Discount Program is achieving this aim.