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

Introduction

On February 2, 2024, a bipartisan group of United States Senators released a letter to stakeholders on issues related to the 340 B Drug Discount Program. The letter was accompanied by a Request for Information (RFI) on key issues and an early draft of legislation designed to clarify the Program's operations. The letter is a follow-up to a July 2023 RFI on the same topic. The Senate letter reflects concerns about whether the 340 B Program effectively meets its purposes and is sufficiently accountable in its operations. The RFI contains specific questions about the program's operations and accountability. The Senate seeks comment on these matters and solicits recommendations on improving the 340 B Program.

In this communication, the National Organization of State Offices of Rural Health (NOSORH) provides input in response to the latest RFI. NOSORH's comments highlight the 340 B Drug Discount Program's important role in helping 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 improving access to and quality health care for over 60 million rural Americans. All 50 states have a SORH, and each SORH helps their rural communities build effective healthcare delivery systems. NOSORH and its members work closely with rural healthcare 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 by the Senate's continued exploration of 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 effectiveness. NOSORH also believes that appropriate monitoring and accountability detailing *all* the impacts of the Program can resolve questions about the program's impact.

Overview – Importance of the 340 B Drug Discount Program

NOSORH understands that multiple groups have expressed concerns about using *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 use 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 these studies accurately reflect how the 340 B Program operates in rural hospitals and other rural health service providers.

In these comments, NOSORH will describe how rural health service providers use 340 B Drug Discount Program savings for three important purposes:

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

NOSORH will also provide comments on the following:

- 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,
- how 340 B Drug Discount Program monitoring and accountability could be improved, and
- how the term *patient* should be defined for the 340 B Program purposes.

Issue: Appropriate Use of 340 B Drug Discount Program Net Savings

Discussion: 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 ***maintaining essential services that would otherwise be unsustainable***. NOSORH considers this to be the main benefit of the Program.

Healthcare providers in many rural communities operate in a low-volume environment 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. Sustaining essential services in rural communities is an important health policy goal. 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 ensure that these services can be provided. The cost of this needed infrastructure can be significant. Other funding sources are needed to ensure these services can be maintained.

Rural healthcare providers' sustainability–particularly 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 important to the supplemental funding needed to maintain essential rural health services. Any reduction of 340 B Program savings to rural providers could compound financial sustainability problems.

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 essential services could be significantly reduced or eliminated.

Maternity and obstetric care services in rural communities are a 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 from Medicaid programs, a major source of maternity coverage nationwide. 340 B Program savings help offset the unreimbursed care costs for obstetric and maternity services.

Financial 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 on PPS rates

negotiated with state Medicaid programs. These rates are set at a level typically about 80% of the actual service cost. Federal grants to FQHCs can help defray some of these losses, but 340 B Program savings and other funding are needed to sustain FQHC services for their Medicaid patients.

Financial support for *uncompensated* care: All rural healthcare 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 cannot 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 Program savings are 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) significantly impacts rural health service providers' uncompensated care. During the PHE, individuals who qualified for Medicaid could 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.

Recommendation: **NOSORH strongly recommends 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 340B Program has focused on a *single* potential use of the net savings – offset of uncompensated care. NOSORH observes that the draft legislation being considered contains such an emphasis. NOSORH believes that the actual use of net savings, particularly by participating rural health service providers, includes multiple other appropriate purposes.

NOSORH strongly recommends that any final guidance recognize the appropriate use of net savings from the 340 B Program for offsetting operational losses of safety net healthcare providers, including low-volume rural healthcare providers. Uses of net

Program savings for losses other than charity care must be considered in an accurate assessment of the Program.

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

Discussion: NOSORH believes that 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 using those savings could better document the program's success.

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 of 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 that does not place an unnecessary burden on participating 340 B Drug Discount Program providers. For example, Schedule H of the IRS 990 form, covering community benefits 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.

Recommendations: NOSORH makes the following recommendations for improvements in 340 B Program accountability:

- NOSORH supports the development of improved reporting for 340 B Program participants. **NOSORH recommends the establishment of reasonable annual reporting requirements for 340 B Program participants** – reporting that documents the net savings of the program as well as the use of these savings for all the purposes described previously – not just the level of charity care.

- **NOSORH recommends that reporting requirements be designed which are not burdensome** for small scale health care providers, including small rural health care providers.

- **NOSORH recommends that the Health Resources and Services Administration (HRSA) consult with representatives of health service providers participating in the 340 B Drug Discount Program** to develop an appropriate annual report format. NOSORH suggests that representatives of *all* categories of eligible health service providers be consulted in this process to improve Program accountability without creating overly burdensome requirements for any class of participating health service provider.

Issue: 340 B Drug Discount Program Contract Pharmacies

Discussion: Rural pharmacies are an important component of the rural health services system. They provide a local source of pharmaceuticals, health supplies, 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 that are more extensive than those of individual participating 340 B Program providers.

NOSORH notes that the service areas of participating rural health care providers are typically extensive and can include communities far from provider service sites. Contract pharmacies throughout the service area are the logical way for participating providers to ensure access to pharmacy services for their patients. These arrangements can eliminate distance barriers for these services for patients remote from provider service sites.

NOSORH notes that 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 inaccessible, patients will delay or forego needed treatment. This will result in poorer health outcomes and increased overall health service costs.

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

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.

Using 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 staff savings. This includes the savings associated with the need to maintain the costly services of a supervising pharmacist.

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

Recommendations: NOSORH makes the following recommendations related to the use of contract pharmacies in the 340 B Program:

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

- NOSORH recommends that studies be conducted evaluating the cost-effectiveness of the use of contract pharmacies, with emphasis on rural areas and pharmacy deserts. Such studies can resolve policy questions about the appropriateness of these arrangements.

- 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: Definition of Patient

Discussion: A recent Federal Court decision regarding the definition of *patient* for purposes of the 340 B Program recognizes that the broadest definition of this term is important in assuring access to services. The key to any definition of patient is an *established relationship* between a participating provider and an individual. NOSORH believes that completion of the patient registration process, including all information components normally used by the provider for patient identification, contact and billing, is the primary indicator of an established relationship between a provider and a patient.

NOSORH does *not* believe that there should be any for length of time requirement in the definition of *patient*. Patients who initially establish a provider relationship during an emergency or urgent episode may have immediate needs for medication to resolve their problems. Their ability to secure needed treatment should not be delayed by any length of time requirement. If the patient is registered with the provider during such an episode, this is sufficient to confirm an established relationship.

Recommendations:

- **NOSORH recommends that any definition of *patient* for purposes of the 340 B Program hinge on whether an individual patient is registered with the participating health care provider.**

- **NOSORH does *not* recommend that the definition of *patient* include any consideration of the length of time of the relationship between the participating provider and a patient. Such restrictions could impede the provision of critical care to patients, including patients of specialty clinics such as sexually transmitted disease and tuberculosis clinics.**