

VIDENCE

Health & Services

October 27, 2015

Mr. James Macrae
Acting Administrator
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, Maryland, 20857

RIN: 0906-AB08
RE: 340B Drug Pricing Program Omnibus Guidance

Dear Mr. Macrae,

On behalf of Providence Health & Services, I want to thank you for the opportunity to provide our formal comments on the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program Omnibus Guidance. For the past two decades, the 340B discount program has been a critical tool for Providence ministries and our affiliated organizations in serving the poor and vulnerable in our communities. As such, preserving the program's integrity and value to our communities is of tremendous importance.

Providence Health & Services is a not-for-profit Catholic health care ministry committed to providing for the needs of the communities it serves – especially for those who are poor and vulnerable. Providence and its secular affiliates, including Swedish Health Services, offer a combined scope of 34 hospitals, 475 physician clinics, home health and hospice, senior services, supportive housing and many other health and educational services. The combined health system employs more than 76,000 people across five states – Alaska, California, Montana, Oregon and Washington.

Providence Health & Services, collectively with our affiliate systems, operates 26 340B-eligible hospitals in Washington, Oregon, California, Montana and Alaska. In addition, we operate numerous other “child sites” and off-campus, hospital-based facilities that are supported through 340B discounts. As a large, integrated health care system providing services to patients across the continuum of care – from primary to acute care to home health and hospice – we are committed to clinical excellence with compassion. We know that quality of life improves when individuals and families have broad access to high-quality, patient-focused, affordable care. Together, Providence ministries and secular affiliates are working at scale to improve overall health in every community we serve through innovation in care delivery, new economic models and expert-to-expert collaboration. Given this perspective, we hope you

find our feedback helpful in finalizing the omnibus guidance. Below are Providence's specific comments on the Omnibus Guidance:

General:

Providence is strongly committed to ensuring that the 340B Drug Discount program continues to be an important policy mechanism to improve access to life-saving drugs to those who are poor and vulnerable in our communities. This includes establishing and updating a regulatory framework that allows Covered Entities to utilize discounts available for the program's intended purpose with the appropriate level of governmental oversight that reflects and is adaptable to the evolving health care delivery system.

The proposed Omnibus Guidance includes a number of provisions that will improve our ability to serve eligible patients in our communities, such as Group Purchasing (GPO) exceptions and the incorporation of the growing opportunity provided by telemedicine. However, we are very concerned that several provisions have the potential to greatly diminish access to 340B-discounted drugs and require our system and others across the country to make wholesale changes in how we are organized to deliver health care to low-income populations.

The proposed guidance would require covered entities to implement new systems for tracking drug purchases based on the use of the drug, the prescriber, the ultimate disposition of a patient, and their Medicaid status. It would also require increasing oversight of contract pharmacies and GPO purchasing violations and would potentially require changes to organizations' relationships with their medical staffs. Providence is concerned about the growing administrative complexity of participating in the 340B Program and would like to reiterate to HRSA that the objective of the program is to stretch scarce resources, not to layer on increasingly complex operational challenges that diminish those resources.

We strongly urge the agency, if it finalizes many of the proposed changes in the guidance, to provide sufficient time for Covered Entities to make the necessary changes to come into compliance. This includes establishing an effective date, which is not specified in the guidance. **We recommend that at a minimum, HRSA allow one year after final guidance is published for Covered Entities to make necessary operational changes to comply with its provisions.**

Definition of Patient of a Covered Entity:

In the guidance, HRSA proposes to clarify that a patient of a Covered Entity will be determined on a "prescription-by-prescription or order-by-order basis" if all of six criteria are met, including:

1. The patient receives a health care service at a facility or clinic that is registered with the 340B program and is listed in the 340B database;
2. The Patient must receive a health care service provided by a Covered Entity (CE) provider "who is either employed the CE or who is an independent contractor for the CE, such that the CE may bill for services on behalf of the provider;"
3. An order or prescription must be the result of a health care service performed by a CE's provider;
4. The individual's health care is consistent with the scope of a Federal grant, project, designation or contract - for those CE's eligible based on such arrangement;
5. The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient;

6. The individual's patient records are accessible to the CE and it can be demonstrated that the CE is responsible for the care of that patient.

While Providence strongly supports HRSA's goal of ensuring that 340B drug discounts apply only to those patients who need them, we are concerned that the proposed definition of a Patient of a Covered Entity is a very significant change in 340B policy that extends too far and would ultimately result in a significant reduction in access for those patients for whom the program is intended. Overall, we believe these changes to the definition of individuals eligible for 340B drugs will result in restricting access to affordable medications, undermining the program's objectives to stretch scarce resources as far as possible for safety net hospitals, and impeding our members' efforts to provide comprehensive services to more low-income patients.

In particular, we offer the following comment on criteria proposed:

Criteria 2 – this proposal is not consistent with what has been historically accepted during Office of Pharmacy Affairs (OPA) audits, and goes against the majority of physician-hospital arrangements for Providence Covered Entities and those of many others across the country. Typically, our Covered Entities have relied upon practitioners having privileges as the basis for satisfying this definition. Moreover, we request that HRSA provide clarification as to how this might apply to Covered Entities that operate as d/b/a's of a larger entity that also operates non-340B eligible sites; in many cases the Covered Entities themselves are not separate legal entities that contract independent of their parent corporation.

The relationship between a hospital and a doctor who provides services in the hospital is irrelevant to determining the relationship between the hospital and the patient receiving those services. The statutory question is whether the individual is a patient of the covered entity.

For services provided outside of the hospital, HRSA should maintain existing practice which allows for 340B discounts when care is referred by the covered entity, that referral is documented in the patient's record, and the off-site provider reports back to the covered entity on the outcome. Under those conditions, it is clear that the patient remains in the care of the covered entity.

In addition, the proposal would pose complex challenges for Providence Covered Entities in California, where hospital-physician alignment is governed by a strong corporate practice of medicine prohibition established in state law. Unlike other states with a similar ban, in California the doctrine mandates the separation of business models, restricting hospitals' ability to bill for physician services that occur within its walls. If this proposal is finalized, hospitals in California could face the possibility of having to discontinue their participation in the 340B program.

Providence strongly urges HRSA not to limit individual eligibility for 340B drugs to those patients receiving their treatment from health care providers who are employed by or an independent contractor of a covered entity such that the covered entity "may" bill for services on behalf of the providers.. If HRSA does finalize this proposal, we request that it clarify what is meant by an entity that "may" bill on behalf of a provider. HRSA must also clarify how this provision, if finalized, would apply in states that do not allow hospitals to employ physicians under "corporate practice of medicine" laws. The proposal as drafted would appear to have the effect of barring hospitals in California and other similarly structured states from the 340B program.

Criteria 3 – This proposed criteria would create significant challenges for our infusion centers and would potentially constrain our ability to provide infusion services to low-income patients. In many cases, our contractual relationships allow for the physicians to bill and retain compensation for their own professional services as part of the arrangement and the Covered Entity only bills for the facility fee. The reassignment of the right to bill, in our view, should not be a required component of Criteria 3.

Patients receiving infusion services from a covered entity must be registered outpatients and receive a range of health care services in connection with infusion services. The covered entity is responsible for and must document all aspects of drug administration, patient assessment, monitoring, instruction, management of adverse events, and all other elements consistent with the care of a patient.

Providence is very concerned that the proposed policy would mean patients would lose access to the infusion services they need, especially rural and low-income patients. In many communities, a local infusion center allows patients who must travel long distances to receive care from specialists such as oncologists, to receive infusion services close to their home instead of having to make many long trips back and forth. These services are of particular importance to vulnerable populations that may find it physically or financially challenging to travel long distances to receive care. Furthermore, this proposed policy could harm low-income patients whose ability to receive affordable cancer treatment depends on the infusion centers they attend participating in the 340B program. Given the significant harm this could cause, we urge HRSA to withdraw these proposed criteria.

Criteria 5 – These criteria, if finalized, would present significant operational challenges for certain outpatient sites as well as potentially reduce our ability to use 340B drugs for discharge prescriptions. Currently, HRSA allows 340B drugs to be used for discharge prescriptions if the drugs are for outpatient use if other program requirements are met, which is determined on a case by case basis. We are very concerned about the unintended consequences of this limitation, particularly on our ability to improve the likelihood that individuals will follow-through with the necessary medications prescribed for them upon discharge from an inpatient stay. Hospitals that are able to provide low-income patients with free or discounted drugs at discharge thanks to the 340B program may no longer be able to do so. If a covered entity is unable to provide a patient with their prescribed medications upon discharge from the hospital, the likelihood that those medications are not obtained rises considerably. We are concerned that forbidding the use of 340B drugs for discharge prescriptions will create the potential for preventable readmissions, as low-income patients may be less likely to fill their necessary prescriptions due to the prohibitive cost of doing so. This outcome would be in direct contradiction to the goals of other existing federal efforts to reduce unnecessary hospitalizations.

We are also concerned about how this provision would apply in other areas where 340B drugs are now available, for example, when a patient is prescribed a 340B drug during treatment in the emergency department and is subsequently admitted to the hospital, or when a patient is within Medicare's 72 hour payment window. If the costs of drugs provided during those periods rises to wholesale acquisition cost or Group Purchasing Organization cost, then that would have the effect of limiting the funds available for charity care – the opposite of the intent of the program.

This provision would also require our hospitals to make significant modifications to our 340B inventory management systems to change how we determine outpatient status, as rules may differ dramatically depending on the commercial insurer. Individual insurer policies concerning patient status can vary greatly and change at any time across the numerous insurers with whom Providence

contracts. Accurately applying the appropriate status to individual patients based on their payer to determine 340B eligibility would prove to be a complex task and a significant operational burden for Covered Entities.

Providence urges HRSA to withdraw this proposed guidance on individual eligibility. HRSA should either maintain the current requirements or propose a new approach, with an additional comment period. Any new proposal to redefine individual eligibility must take into consideration the evolving nature of how health care is delivered and the increased focus on clinical integration and care coordination delivery models. More and more, hospital-managed care is provided in non-hospital locations, including patients' homes, or by telemedicine and involves many types of providers with different relationships to the hospital directing the care. HRSA's guidance of the 340B program should reflect this new reality.

Group Purchasing Organization (GPO) Prohibition:

HRSA notes that the GPO restriction on DSH hospitals and cancer/children's hospitals does not apply to inpatient drugs or those drugs that do not meet the definition of a covered outpatient drug. HRSA also states that where applicable, the prohibition extends to any pharmacy owned or operated by the Covered Entity.

HRSA also proposes that for isolated errors involving the GPO prohibition (non-systemic), the agency will allow as part of the notice and hearing process an opportunity for a Covered Entity to submit a correction action plan to demonstrate that the GPO violation was isolated and the entity is currently in compliance, but if after notice and opportunity for hearing, the violation is determined to not be isolated, the Covered Entity would be immediately terminated. If a parent site is determined to have violated the GPO prohibition, it, all child sites and all contract pharmacies would be removed.

Providence recommends that HRSA clarify under which circumstances the agency would find that a GPO violation was not isolated and allow for the parent site to remain in the program under this exception if it can show that the drugs purchased in violation of the prohibition were only used at one or more child sites, not at the parent, even if they share the same accounts for purchasing.

Contract Pharmacy Arrangements:

In the proposed guidance, HRSA expresses its intent to ensure that contract pharmacy arrangements are strictly meeting compliance requirements, including that all contract arrangements are registered and are in conformance with all registration deadline and effective dates announced in the Federal Register. In addition, HRSA states that a single Covered Entity can only contract with a pharmacy on its own behalf as an individual Covered Entity and "groups or networks of Covered Entities may not register or contract for pharmacy services on behalf of their individual Covered Entity members."

Providence recommends that HRSA provided needed clarification on these provisions. First, HRSA's statement about groups of Covered Entities' not being able to contract collectively for contract pharmacy is unclear and has significant potential implications for system-level contracting arrangements. We submit that whether a contract identifies multiple Covered Entities should not affect its enforceability. Second, it is unclear what steps HHS would take related to contract pharmacy arrangements that it views as being inconsistent with the intent of Congress – specifically as they relate to the anti-kickback statute.

Conclusion:

As noted above, Providence and its affiliation strongly support HRSA's goal of improving oversight of the 340B program and ensuring that drug discounts under the program are afforded for the purpose of providing needed medications for low-income populations. At the same time, the 340B program should be aligned with current and developing models of care and promote healthier communities. We are very concerned that the proposed guidance in many cases is not aligned with either the original intent of the statute or reflective of the evolving health care delivery system. Moreover, in several areas the proposed guidance will reduce patient access to needed medications and hinder our ability to effectively serve the poor and vulnerable in our communities.

We urge HRSA to move slowly in finalizing and implementing these proposed changes to the program, in some case withdrawing provisions (highlighted above) that risk undermining the goals of the 340B program by creating barriers for Covered Entities to serve their communities.

Thank you for the opportunity to provide comments to the omnibus guidance for entities enrolled in the 340B program and drug manufacturers. If you have any questions about these comments or need more information, please do not hesitate to contact Steve Brennan, Director, Public Policy, at Steven.Brennan@providence.org.

Sincerely,

Rod Hochman, M.D.
President and Chief Executive Officer
Providence Health & Services