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October 26, 2015

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Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Submitted electronically via http://www.regulations.gov

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

Dear Captain Pedley,

Trinity Health appreciates the opportunity to provide comments on the Health Resources and Services Administration's (HRSA) proposed guidance that addresses changes to eligibility and compliance related to participation in the 340B Drug Pricing Program (340B Program). Our comments and recommendations to HRSA reflect a strong interest in 340B Program policies that support continued access to 340B drug pricing to enable 340B-participating covered entities to stretch scarce federal resources and to preserve the integrity of the 340B Program.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving more than 30 million people in 21 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming, and healing presence in our communities. Trinity Health includes 44 340B-participating covered entities, including 19 owned disproportionate share hospitals, 2 owned sole community hospitals, 5 owned critical access hospitals, 10 managed critical access hospitals and 8 non-hospital covered entities that include clinic and health center programs.

Committed to those who are poor and underserved, Trinity Health returns almost $1 billion to our communities annually in the form of charity care and other community benefit programs. Our hospitals use savings from the purchases of 340B drugs to support a variety of crucial programs consistent with the purpose of the 340B Program. Most importantly, the 340B Program allows us to offer more comprehensive patient services to the most vulnerable uninsured and underinsured patients in our communities. For example, we have used 340B savings to open new outpatient pharmacies that, due to access to the reduced 340B prices, are able to dispense free or reduced cost prescriptions to low income patients. We have also used 340B savings to support additional ambulatory care pharmacists at certain outpatient clinic locations, which has allowed us to increase access to essential, often non-reimbursed, services such as anticoagulation, heart failure, smoking cessation and discharge clinics for

these vulnerable populations. One of our hospitals has been able to use 340B savings to support an increase in the volume of such services from 200 patients per month to over 500 patients per month. At our ministries across the country, the 340B Program is supporting improved patient care, increased patient medication access and adherence, and decreased hospital readmissions.

We thank HRSA for the opportunity to comment on the proposed guidance and intend for our comments and recommendations to reflect our strong interest in 340B Program policies that support continued access to 340B drug pricing to enable 340B-participating covered entities to stretch scarce federal resources and preserve the integrity of the 340B Program.

If you have any questions on our comments that follow, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,

Tonya K. Wells
Vice President, Public Policy & Federal Advocacy
Trinity Health

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Part A- 340B Program Eligibility and Registration
(FR Vol. 80, No. 167 [52301-52305, 52316-52319]

Group Purchasing Organization (GPO) Prohibition for Certain Covered Entities

Trinity Health appreciates HRSA's formal recognition of exceptions to the GPO prohibition. In order for hospital covered entities subject to the GPO prohibition to continue to meaningfully participate in the 340B Program, it is important for HRSA to acknowledge the challenges of absolute compliance with the GPO prohibition. Even with comprehensive compliance monitoring programs, hospital covered entities may encounter clinical needs to purchase covered outpatient drugs through a GPO or may inadvertently dispense a GPO-purchased covered outpatient drug to an outpatient.

As to the proposed exceptions to the GPO prohibition regarding changes in patient status, Trinity Health requests that HRSA clarify that this exception extends to patient status changes from inpatient to outpatient that result from a hospital's own internal utilization review processes, and is not limited to patient status changes made by external or third-party reviewers.

In light of HRSA's recognition that an expectation of absolute compliance with the GPO prohibition is not required by the 340B statute, Trinity Health encourages HRSA to provide for reasonable application of the GPO prohibition to hospital covered entities subject to the GPO prohibition. Specifically, HRSA should implement a materiality threshold, below which covered entities would not be subject to ineligibility to purchase 340B drugs or removal from the 340B Program. Where erroneous GPO purchases do not exceed such a materiality threshold, HRSA should permit corrective action through credit/rebill (or other adjustment) of the GPO purchases, rather than directing refund of 340B purchases back to the date of the first erroneous GPO purchase. Under the proposed guidance, negligible GPO

purchases of covered outpatient drugs have the potential to result in grossly disproportional obligations to refund 340B purchases.

Trinity Health supports HRSA's acknowledgement that there are many circumstances that may result in erroneous GPO purchases of covered outpatient drugs and that it is not appropriate to treat all such purchases in the same manner. However, in order for hospitals to understand the expectations of compliance with the GPO prohibition and the corrective actions that may be applied in the event that a violation occurs, HRSA must provide a clear definition of "isolated" and "systemic" non-compliance. In light of the significant penalties that HRSA intends to impose for even isolated non-compliance, hospitals must be assured that HRSA is applying clear, defined and objective criteria to evaluate non-compliance and impose corrective actions.

Eligibility of Off-Site Outpatient Facilities and Clinics

Trinity Health is pleased that HRSA is requesting comments for alternative approaches to determining eligibility for off-site outpatient hospital locations. Consistent with the 340B statute, we encourage HRSA to implement an approach that recognizes eligibility for all locations that are within the definition of "hospital" as used for purposes of the application of Social Security Act § 1886(d). As currently applied and as proposed, HRSA imposes arbitrary limits on 340B eligibility based on a misunderstanding of what is and is not part of a hospital. While we appreciate that HRSA would prefer an approach to eligibility that relies on objective factors evaluated by the Centers for Medicare and Medicaid Services (CMS), we believe that HRSA is correct to identify in the proposed guidance the challenges with using such approaches. Although the 340B statute refers to eligible hospitals in reference to Medicare program hospital designations, HRSA's proposed approach cuts off 340B eligibility to certain locations of a hospital that would be considered part of the hospital by CMS. For example, under HRSA's proposed guidance, off-site outpatient clinics serving pediatric or obstetrics patients could be found ineligible to purchase and dispense 340B drugs if they did not see any Medicare patients in the prior year, even though these types of clinics typically would not be expected to ever see any Medicare patients.

Trinity Health recommends that HRSA deem as 340B-eligible those locations of a hospital that are determined by CMS to be part of the hospital for purposes of the hospital's Medicare certification. It is our understanding that CMS views all locations of a hospital that may furnish services to Medicare or Medicaid patients to be part of the hospital. Further, CMS does not postpone determination of whether a location is part of a hospital until after it appears on a filed Medicare cost report. HRSA's current and proposed policy of delaying 340B eligibility until a location appears on a filed Medicare cost report is not required by the 340B statute, is inconsistent with CMS practice and does little to protect the integrity of the 340B Program. Trinity Health strongly encourages HRSA to adopt a final policy that provides for 340B eligibility of all locations of a hospital as soon as the hospital commences delivery of clinical services at the location.

Part B- Drugs Eligible for Purchase Under 340B
(FR Vol. 80, No. 167 [52305-52306; 52319]

Only "covered outpatient drugs" are eligible for discounted 340B pricing. HRSA is proposing to interpret the definition of "covered outpatient drug" such that drugs that are billed and paid for by Medicaid as part of a bundled payment would be excluded from the definition of covered outpatient drugs. HRSA would classify as covered outpatient drugs those outpatient drugs that are billed and paid separately by any payer, and drugs that are billed and paid as part of a bundled payment by any payer other than Medicaid.

While Trinity Health appreciates HRSA's attempt to clarify the definition of covered outpatient drug in a manner that can be consistently applied objectively across covered entities, the proposed definition will create significant, and in some cases insurmountable, administrative burdens for our covered entities. As proposed, our covered entities could not make a determination regarding the 340B or GPO eligibility status of the drug at the time of dispensing or billing and, due to claims submission policies and certain Medicaid eligibility policies, it is possible that the determination could not be made for many months after the drug was administered.

The result of this policy is that we would no longer be able to maintain physical inventories of 340B and non-340B drugs at any location, and would be required to devote financial and administrative resources to implementation of virtual inventories at locations currently maintaining a physical inventory. Delays in identification of the appropriate drug classification may also result in increases in non-340B/non-GPO purchases if the covered entity is unsure of the appropriate drug category in a timely manner. Such financial and administrative burdens will result in diversion of resources from patient care services to administrative and drug costs and are completely avoidable under alternative definitions of covered outpatient drug. One of our hospitals used their most recent inventory turnover rate and value to determine that each week of drug inventory on hand carries a cost of $313,642. This hospital estimates delays in determining appropriate drug classification required to maintain compliance with these new guidelines will necessitate an additional 3-4 weeks of inventory costing $940,929 to $1,254,568. This is an average size hospital with representative services, which suggests similar increases would not be uncommon at many institutions.

Trinity Health recommends that HRSA maintain its current and long-standing policy of permitting each covered entity to interpret the definition of covered outpatient drug, so long as the covered entity's interpretation is defensible, consistently applied, documented and auditable. Alternatively, Trinity Health requests that HRSA implement a policy that would permit covered entities to establish written expectations regarding billing and coverage rules for certain payers and drugs. Such written expectations could be used by a covered entity to deem as 340B or GPO eligible those drugs that are classified at the time of dispensing in a manner consistent with the written expectations.

Part C- Individuals Eligible To Receive 340B Drugs
(FR Vol. 80, No. 167 [52306-52308; 52319]

Trinity Health recognizes the need for HRSA to propose a definition of patient that provides for a clear and consistent approach to identifying patients of a covered entity who are eligible to receive 340B drugs. We are disappointed, however, in HRSA's decision to propose a definition of patient that restricts access to 340B drugs for many legitimate patients of hospital covered entities.

By focusing too narrowly on the relationship between the prescription and the covered entity, rather than the patient and the covered entity, the proposed definition limits 340B eligibility to only a portion of patients of a covered entity who should be eligible to receive 340B drugs. This change in policy appears to represent a misunderstanding by HRSA of the relationship between certain patients and covered entities, and is inconsistent with the 340B statute, which focuses the analysis at the patient level, not the prescription level. The 340B statute does not require such a relationship between an individual and a covered entity at the time a prescription is written, and, notably does not specify whether an individual must have been an *out*patient of the covered entity at all. The statue requires only that covered entities "not resell or otherwise transfer [covered outpatient drugs] to a person who is not a patient of the entity." (42 U.S.C. § 256b(a)(5)(B)).

Trinity Health strongly objects to the proposed requirement that an individual receive health care services from a health care provider who is employed by or an independent contractor of a covered entity in order to be considered a patient of the covered entity. This requirement does not reflect the manner in which many health care services are delivered in our hospitals. The determination of whether a patient is a patient of a hospital does not take into consideration the relationship between the provider furnishing services and the hospital. It is not uncommon for our hospitals to permit privileged and credentialed practitioners to furnish services in our hospitals to our hospital patients. For example, a patient may come to our hospital for a surgical procedure that is performed by a surgeon who is privileged and credentialed at the hospital, but is neither employed by or under contract with the hospital. There is no question that the patient is a patient of our hospital and should be eligible to receive 340B drugs. Similarly, the language indicating that the covered entity "may bill for services on behalf of the provider" also appears to misunderstand the relation between the status of a patient as a patient of a hospital and the arrangement under which their provider is furnishing care in the hospital. In the surgery example above, the hospital would not be permitted to bill for the surgeon's professional services, although would bill for the hospital facility services associated with the procedure. The fact that the hospital does not bill for the surgeon's service has no bearing on whether the patient is a patient of the hospital.

Under the proposed definition, our covered entities would be unable to fill discharge prescriptions with 340B drugs, and would be unable to obtain drugs for certain infusion services at 340B prices. We do not believe that either of these restrictions on 340B dispensing are consistent with the intent of the 340B Program.

The proposed policy represents a material and arbitrary change from HRSA's current position on discharge prescriptions. Under current HRSA guidance, discharge prescriptions may be filled with 340B drugs, so long as the covered entity is able to demonstrate that the drugs are for outpatient use, the covered entity remains responsible for the use of the drugs on an outpatient basis, and the entity retains auditable records to demonstrate compliance with current 340B Program requirements.[1] Such prescriptions, written prior to discharge from inpatient status, but filled post-discharge, are written for individuals who are unquestionably patients of the covered entity at the time the drug is prescribed and are appropriately classified as outpatient drugs because they are filled post-discharge. Implementation of this proposed change would have an adverse effect on the patients served by Trinity Health's 340B-participating hospitals.

Ensuring that discharged patients fill prescriptions for discharge medications is an essential component in reducing readmissions and improving patient outcomes. Trinity Health has determined that the reason many discharge prescriptions go unfilled is that patients cannot afford to fill the prescriptions. In recognition of this barrier, Trinity Health has implemented a program to offer free discharge prescriptions to patients who would otherwise be unable to afford to fill the prescription. Trinity Health is able to offer this program because of the discounted 340B prices that it currently receives for these discharge prescriptions. One institution has implemented an optional patient service to provide their new discharge medication prescriptions as they leave the hospital to assure there are no breaks in care. The service was expanded after pilot data showed an 83 percent lower 30 day readmission rate among heart failure patients who left the hospital with their medications versus those who took prescriptions to fill on their own. The service is now chosen by 72 percent of all discharged patients. If HRSA were to implement the proposed policy to cut off access to 340B pricing for discharge

[1] See Health Resources and Services Administration, Office of Pharmacy Affairs, Frequently Asked Questions, http://www.hrsa.gov/opa/faqs/index.html (last accessed 9/27/2015).

prescriptions, Trinity Health hospitals would struggle financially to maintain this program of providing free discharge prescriptions and may find provision of patient-centered and convenient discharge prescription services to be financially prohibitive. One of our hospitals has estimated that elimination of discharge prescriptions from 340B eligibility may require as much as a 50 percent reduction in the volume of prescriptions that they are currently providing at a free or at reduced rates. Across our hospitals it would significantly reduce, and in some cases eliminate, our ability to support discharge prescription programs for poor and underserved patients, which we know will result in significantly decreased patient medication access, reduced medication adherence, increased readmissions, and negatively affect patient care.

The proposed policy also represents a material and arbitrary change from HRSA's current position on infusion drugs. Under current HRSA guidance, infusion drugs may be obtained at 340B prices, so long as the patient receives health care services other than drug administration from the covered entity.[2] 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. CMS recognizes as primary services, the following classes of infusion services; Chemotherapy IV infusion, Chemotherapy IV push, Drug Admin IV infusion, Drug Admin IV push, and Hydration IV infusion. Secondary services are recognized for additional drugs and additional services. These services are provided under the "incident to" rule and hospital personnel must provide the services and supplies as documented on a physician's order and under hospital medical staff supervision. The physician who orders the hospital service is not required to be directly connected with the department that provides the service. There are very specific documentation requirements for the treatment order, medical necessity, and nurse's documentation of administration. The treatment documentation must support the selected service line complexity, drug classification, mode of administration, access site, start and stop time, rate of administration, dose or volume administered, and flushing or clearing of a line. Documentation also includes patient assessment, monitoring, instruction, management of adverse events, and all other elements consistent with the care of a patient. Treatment of a patient in an infusion center should be regarded as sufficient care to make that patient a qualified patient of the covered entity without regard to the relationship with the physician who ordered treatment.

The proposed change to the definition of patient to limit 340B pricing for infusion drugs will adversely impact patients who receive infusion services at our hospitals. We currently rely on savings from 340B pricing to provide infusion services in our communities. Comparison of Medicare reimbursement rates for the top 20 drugs infused in one of our hospital's infusion centers indicates 40 percent of the current rates are lower than the actual acquisition cost at GPO rates and almost all are reimbursed below wholesale acquisition cost. Many commercial carriers pay close to the same rates. The proposed narrowing of patient status for drugs which require administration in an infusion center is very likely to reduce patient access to care as covered entities determine that continued access to hospital based infusion centers by patients that do not fit the narrowed definition of 340B eligible patients will result in significant financial exposure. In many of the communities where we operate our infusion services allow for patients to receive infusion services close to their home, rather than traveling to another hospital many miles away. These services are of particular importance to vulnerable populations that may find it physically or financially challenging to travel long distances to receive care. If we are no longer able to purchase drugs for infusion services at 340B prices, we may be forced to close certain of our infusion services.

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[2] See Apexus, Frequently Asked Questions, FAQ 1286 (11/20/2014), https://www.340bpvp.com/resource-center/faqs/ (last accessed 9/27/2015).

We urge HRSA to remove from the final definition those elements of the proposed definition of patient that require a patient to be an outpatient of a covered entity at the time a prescription. Instead, we believe that a definition of patient that focuses on the relationship between the patient and covered entity at the time the 340B drug is dispensed is more consistent with the 340B statute and provides for the necessary safeguard of the integrity of the 340B Program.

Trinity Health also has concerns regarding HRSA's proposal to determine patient status based on payer billing rules. Under HRSA's current policy, the determination of whether a patient is an inpatient or outpatient is made by the covered entity. A policy that relies on payer billing rules will result in significant challenges in determining eligibility for 340B drugs at the time of administration. We do not believe that our current information systems will permit us to determine patient status for 340B eligibility at the time of administration and that we would be forced to delay determination of 340B eligibility until after services have been billed and paid.

The consequence of this policy is that we will no longer be able to maintain physical inventories of 340B and non-340B drugs at any location, and would be required to devote financial and administrative resources to implementation of virtual inventories at locations currently maintaining a physical inventory. Delays in identification of the appropriate drug classification may also result in increases of our non-340B/non-GPO purchases if billing cycles or payer billing rules prevent us from determining the appropriate patient status (and, therefore, drug category) in a timely manner. Such purchases would be avoidable under an alternative approach to identifying outpatients, and will result in diversion of resources from patient care services to increased administrative and drug.

We recommend that HRSA retain the current policy of permitting covered entities to make patient status determinations based on existing objective patient status policies. The current approach is consistent with existing payer policies regarding patient status, which do not rely on billing rules to determine patient status at the time services are delivered. For example, under current Medicare policy, patient status rules are distinct from billing rules. For Medicare program purposes, a patient does not become an inpatient until an order for inpatient admission is written, although certain pre-admission outpatient services may be bundled into a single inpatient payment for Medicare payment purposes.

Finally, Trinity Health requests that HRSA recognize the increasing focus on coordinated care delivery models across care settings and the important role that these models play in improving patient outcomes. In many of these models, including those in which Trinity Health actively participates, our practitioners provide care coordination and clinical services to patients in the manner that is most appropriate to the needs of the patient, taking in to account controlling costs and improving quality. As a result, our practitioners may provide services to a patient in the patient's home or via telephone in order to prevent the patient from having to travel to a hospital location. Under the proposed definition of patient, even though the patient in these examples is a patient of the hospital and their care is being actively managed by the hospital, prescriptions generated under such incidents of care would be ineligible for 340B pricing because the patient did not receive the service at a 340B-enrolled hospital location. The proposed patient definition is inconsistent with such quality and value driven care and payment models, which are increasingly common and are being actively pursued by the Department of Health and Human Services.[3] While we understand that the 340B statute limits dispensing of 340B drugs to patients of a covered entity, we believe that HRSA should implement a definition of patient that

[3] U.S. Department of Health and Human Services, "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value," January 26, 2015, available at: http://www.hhs.gov/news/press/2015pres/01/20150126a.html.

accommodates 340B eligibility within innovative and quality-focused care models, rather than restricting 340B eligibility to traditional, fee-for-service care and payment models. Requiring that a visit take place at a 340B-enrolled location is not required by the 340B statute and creates a disincentive to furnishing care in a manner that is most beneficial to the patient and consistent with the direction in which our health care system is moving.

Trinity Health strongly encourages HRSA to adopt a definition of patient that is clear, objective and capable of uniform application, but that recognizes the varying arrangements between an individual and a covered entity that may create a provider-to-patient relationship. Specifically, Trinity Health recommends a definition of patient that incorporates the following principles: (1) patient status at the time a prescription is written should not be a relevant factor in determining 340B eligibility for covered outpatient drugs when the prescription is written to a registered hospital patient, when the patient is physically located at the hospital and by a practitioner who is authorized by law and hospital policy to practice at the covered entity; (2) covered outpatient drugs should be eligible for 340B pricing whenever dispensed to an individual who is a registered outpatient of a covered entity at the time of dispensing and is receiving a health care services from the covered entity beyond drug dispensing; and (3) outpatient status should be determined at the time of drug dispensing and based on covered entity-established policies to be applied across all payers.

Drug Inventory/Replenishment Models

In its discussion of drug accumulation under replenishment models, HRSA proposes that a covered entity violates the 340B Program prohibition on drug diversion if it improperly accumulates 340B drug inventory, even if such accumulation occurs prior to purchase of a 340B drug. Trinity Health has significant concerns with HRSA's proposed policy. HRSA's proposal reflects a fundamental misunderstanding of replenishment models and, if implemented, would result in covered entities being found to have committed drug diversion in instances where no purchases of 340B drugs occurred.

Trinity Health agrees that erroneous accumulation to a 340B account and subsequent purchase of 340B drugs based on the erroneous accumulation could result in a finding of drug diversion. However, under HRSA proposed policy, a covered entity that erroneously accumulates 340B drugs could be found to have engaged in drug diversion even if it corrected the erroneous accumulation before any 340B purchases were made on the account. Trinity Health is challenged to understand how a covered entity is appropriately found to have engaged in diversion where no purchases of 340B drugs are made.

Trinity Health strongly disagrees with HRSA's proposed policy to consider accumulation errors as non-compliant purchases where no drug purchasing actually occurs as a result of the erroneous accumulation. Consistent with the 340B statute, we recommend that HRSA consider only actual drug purchases when evaluating compliance with 340B Program requirements.

Part D- Covered Entity Requirements
(FR Vol. 80, No. 167 [52308-52310; 52319-52320]

Medicaid Managed Care

Trinity Health appreciates that HRSA's proposed guidance attempts to clarify covered entity responsibilities regarding prevention of duplicate discounts and Medicaid managed care organization (MCO) patients. Trinity Health is particularly supportive of HRSA's proposal to permit covered entities to select different "carve in/out" policies for Medicaid fee-for-service and MCO enrollees. Under the

proposed guidance, covered entities are expect to be able to identify Medicaid MCO patients and must refrain from dispensing 340B drugs to Medicaid MCO patients under contract pharmacy arrangements unless the arrangement incorporates HRSA-approved, state and MCO-specific safeguards to prevent duplicate discounts. However, HRSA's proposed guidance does not recognize limits of current methods for identifying Medicaid MCO patients, making it impossible for covered entities to ensure that all Medicaid MCO patients are identified.

In the proposed guidance, HRSA states that "covered entities should have mechanisms in place to be able to identify MCO patients." While we would welcome the ability to implement such mechanisms, we do not believe that reliable mechanisms currently exist to identify Medicaid MCO patients in the retail pharmacy setting. Although HRSA asserts in the proposed guidance that there are existing data elements that can be used to identify Medicaid MCO patients, we do not agree with HRSA's understanding of the use of these data elements. For example, as recognized in the proposed guidance, Bank Identification Number (BIN) is one method that could potentially be used to identify Medicaid MCO patients. In practice, however, MCOs often use the same BIN for both commercial and Medicaid plans. Therefore, we are unable to rely on the BIN to identify Medicaid MCO patients.

Under the proposed guidance, until Medicaid MCOs develop reliable data elements to identify Medicaid MCO patients, we believe covered entities will be required to discontinue dispensing of 340B drugs directly to hospital outpatient and indirectly through contract pharmacy arrangements or risk violation of the prohibition on duplicate discounts. Therefore, we recommend that HRSA impose the obligation for the prevention of duplicate discounts as to Medicaid MCO patients on states and Medicaid MCOs, and that such obligation continue at least until such time as the states and Medicaid MCOs develop and implement a uniform and reliable mechanism for identification of Medicaid MCO patients and pharmacy claims.

Maintenance of Auditable Records

Trinity Health understands the important role that auditable records play in ensuring the integrity of the 340B Program. In light of the significant importance that HRSA places on auditable records in the proposed guidance and given that HRSA would make failure to retain auditable records grounds for potential removal from the 340B Program, it is essential that HRSA provide clear guidance regarding the specific data elements and format that are expected as to compliant auditable records. We strongly encourage HRSA to provide such clarity in the final guidance.

We request further clarity regarding the reference to the five year record retention requirement in the proposed guidance. We appreciate HRSA's recognition of the need for a defined record retention term and the role that such a period plays in establishing expectations for record retention. Record retention periods are also generally viewed as providing a back-stop date for findings of non-compliance, as in the normal course of reviews it would be unreasonable to cite an entity for non-compliance during a period for which it does not have records to support compliance. Therefore, we are concerned by the statement in the proposed guidance that HRSA may opt to look back more than five years during an audit. This statement is wholly inconsistent with the expectation that covered entities only retain records for five years. We request that HRSA apply a consistent record retention period and audit look-back period of no more than five years.

Part E- Contract Pharmacy Arrangements
(FR Vol. 80, No. 167 [52310-52311; 52320-52321]

Trinity Health recognizes the need for close oversight of contract pharmacy arrangements to ensure compliance with 340B Program requirements and appreciates HRSA's efforts to ensure that program integrity is maintained under such arrangements.

Trinity Health has concerns regarding the proposed expectations for burdensome and unnecessary oversight of such arrangements. Current HRSA guidance includes annual independent audits of contract pharmacy arrangements.[4] The proposed guidance would add to this requirement by imposing quarterly reviews and including within the scope of such reviews all contract pharmacy locations.

The proposed policy change will require devotion of significant administrative and financial resources that could be devoted to providing patient care services within our communities. We do not believe that it is necessary to evaluate each pharmacy location on a quarterly and annual basis. Our contract pharmacy arrangements are being consolidated under common policies and with common software. Due to the automated nature of the administration of contract pharmacy arrangements, it is highly unlikely that unique compliance issues would arise at a specific pharmacy location. Evaluation of a sample of claims across pharmacy locations or at a single pharmacy location is sufficient to detect program compliance risks. Further imposing both quarterly and annual reviews, particularly covering pharmacy locations operated by the same vendor, is unnecessarily burdensome and duplicative.

As currently proposed, the expectations regarding the contract pharmacy reviews are unclear. While HRSA has proposed to require maintenance of auditable records of the reviews, which effectively converts the contract pharmacy reviews from an expectation to a program eligibility requirement, HRSA has not provided clear information as to what specific compliance elements must be reviewed, what sample sizes must be reviewed or what review methodologies may be acceptable.

We recommend that HRSA revise the proposed policy to clarify the review expectations and to require only reviews consistent with the size and scope of a covered entity's overall 340B Program and contract pharmacy arrangements. Smaller programs may not require quarterly and annual reviews, while larger programs may require more frequent reviews. Similarly, HRSA should not require review of all contract pharmacy locations. A more appropriate metric would be to require review of a sample of claims by pharmacy chain or by software vendor.

Part F- Manufacturer Responsibilities
[FR Vol. 90, No. 167 [52311-52313; 52321-52322]

While Trinity Health is strongly supportive of HRSA's recognition of the challenges that manufacturer limited distributions plans may place on access to 340B drugs, we do not believe that HRSA's proposed guidance goes far enough to ensure that manufacturers do not limit access to 340B drugs through limited distribution plans. We encourage HRSA to require that manufacturers obtain HRSA approval before implementing a limited distribution plan, rather than merely requiring that manufacturers notify HRSA prior to the implementation of such plans. HRSA must ensure that such plans not exclude covered entities from accessing drugs at 340B prices and should require that covered entities have access to 340B drugs and in a manner that is no more restrictive or burdensome than prior to the implementation of the plan. Further, to the extent that any such plans require that covered entities contract with a manufacturer-designated specialty pharmacy in order to access 340B pricing, the contract pharmacy registration periods should be waived for such arrangements and covered entities

[4] See Health Resources and Services Administration, Office of Pharmacy Affairs Update, Contract Pharmacies, June 2015, http://www.hrsa.gov/opa/updates/2015/june.html (last accessed 9/27/2015).

must not be charged dispensing fees under such arrangements. Finally, we encourage HRSA to impose penalties for manufacturers that fail to comply with HRSA guidance regarding access to 340B drugs under limited distribution plans including, but not limited to, credits to covered entities for 340B discounts on drugs that the covered entity was required to access non-340B prices during periods of limited access to the drug.

Part G- Rebate Option for AIDS Drug Assistance Programs
[FR Vol. 80, No. 167 [52313-52314; 52323]

Trinity Health supports HRSA's proposed approach to allocating responsibility for prevention of multiple 340B discounts and rebates as it relates to patients of AIDS Drug Assistance Programs (ADAPs). Our hospitals have found it challenging to ensure that multiple 340B discounts do not occur when dispensing drugs to patients of ADAP programs. The proposed guidance provides our hospitals with the necessary assurance that responsibility for prevention of multiple discounts is the responsibility of the ADAP program and not of our hospitals. As a result, we will be able to begin dispensing 340B drugs to ADAP patients and will be able to do so without risk of creating multiple discounts. By being able to expand our 340B programs to these additional patients, we anticipate being able to augment our existing services to this particularly vulnerable patient population.

Part H- Program Integrity
[FR Vol. 80, No. 167 [52314-52316; 52322-52323]

Throughout the proposed guidance, HRSA references instances of non-compliance that require disclosure to both drug manufacturers and to HRSA. Unlike current program guidance and the annual recertification statement, which provide for a *de minimus* reporting threshold to HRSA, the proposed guidance is silent regarding such a reporting threshold. Trinity Health strongly encourages HRSA to maintain a *de minimus* reporting threshold for self-disclosure of non-compliance to HRSA and that HRSA explicitly provide for such a threshold in the final guidance.

HHS Audit of a Covered Entity

Trinity Health appreciates HRSA's recognition that a notice and hearing process is required prior to imposing penalties on covered entities for diversion and duplicate discounts identified during audits, as well as HRSA's extension to such a process to other circumstances where HRSA proposes to take adverse actions against covered entities for 340B Program non-compliance. Trinity Health is opposed to HRSA's interpretation of the statute that permits it to engage in the notice and hearing process described in the proposed guidance. A process through with the only opportunity for a "hearing" is the covered entity's submission of written materials to respond to HRSA's allegations of non-compliance, which are then reviewed by HRSA, provides insufficient opportunity for a meaningful and objective review process. Trinity Health strongly believes that HRSA must implement a process that incorporates written and oral response by the covered entity, review of the covered entity response to HRSA's allegations by a non-HRSA entity and determination of the final outcome by a non-HRSA entity. Trinity Health also strongly encourages HRSA to establish a formal process for appeal of adverse audit findings through the HHS administrative appeals processes.

Manufacturer Audit of a Covered Entity

While Trinity Health acknowledges that the 340B statute provides for manufacturer audits of covered entities, we believe that the proposed guidance does not provide sufficient protections on covered entities as related to such audits. We recommend that HRSA explicitly limit the scope and volume of

documents that manufacturers may request from covered entities and that all document requests be subject to covered entity appeal to HRSA for review of administrative burden in document production. We are also concerned with HRSA's proposed time limit of one year on manufacturer audits. Such a time period is unreasonably burdensome on covered entities and we cannot conceive of circumstances under which a manufacturer would require one year to audit a covered entity. We encourage HRSA to impose a more reasonable time period, for example, three months.

Implementation Period

Although not addressed in the proposed guidance, we believe that on issuance of the final guidance it is essential that HRSA provide an explicit time period for implementation of new 340B Program guidance such that covered entities have sufficient time to come into compliance with any new compliance expectations. We believe that a period of one year following the effective date of any final guidance is an appropriate time period to give covered entities time to comply, but also believe that HRSA should provide for opportunity for a process by which covered entities may request additional time, if necessary, to implement necessary program changes or software updates. We also believe that any record retention requirements should be phased in over time, such that covered entities are not penalized for failing to maintain records for periods of time not subject to retention prior to the effective date of any final guidance.