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Public Health Service Act, Section 340B:

340B Drug Discount Program

Compliance Risks Associated With Contract Pharmacy Arrangements

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INTRODUCTION

The 1980's was marked by rapid escalation in health care costs.[1] In 1989, Medicaid State Agencies paid more than $3.6 billion for prescription drugs.[2] In an attempt to reduce the federal deficit, Congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), which created the Medicaid Drug Rebate Program (MDRP).[3] Prior to the creation of the MDRP, pharmaceutical manufacturers could voluntarily offer state Medicaid program discounts on prescription drugs purchased by Medicaid patients.[4] The passage of OBRA 90 made it mandatory for pharmaceutical manufacturers to offer discounts to the government if they wanted to sell their products to these patients.[5] In 1992, Congress realized that there was an imbalance with the discounts offered to other agencies of the federal government, so they created the Veterans Health Care Act of 1992 (VHCA).[6] Title VI of the VHCA amends the Federal veterans' benefits law to require agreements between The U.S. Department of Health and Human Services Department (HHS) and pharmaceutical manufacturers to limit the purchase price of drugs procured by the VA and certain other Federal agencies.[7]

CREATION AND PURPOSE OF 340B

Section 602 of the Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act (PHS Act).[8] Congress meant for the savings from 340B-purchased drugs "to enable covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." [9] The congressional record states the intent of the program was to extend Medicaid drug discounts to the most vulnerable of patients of safety net health care organizations, those who are mostly, "medically uninsured, on marginal incomes and have no other sources to turn to for preventive and primary care services." [10] The executive purpose was that additional program resources would be generated if drug acquisition costs were lowered, but revenue from grants or health insurance reimbursements were maintained or not reduced as much as the 340B discounts or rebates.[11] The 340B program does not make a particular patient category eligible for the program; rather, the program makes safety-net providers eligible for the program because of their dedication to serving the low-income and most vulnerable patients.[12]

PROGRAM PARTICIPANTS

COVERED ENTITY

A covered entity must meet specific requirements based on their entity type in order to qualify for the program.[13] Hospitals must be a Disproportionate Share Hospital (DSH) and serve low income Medicare and Medicaid patients.[14] DSH hospitals must have a disproportionate share adjustment percentage greater than 11.75, can be private or non-for-profit with a contract with the government agency to provide services to low income patients who are not entitled to Medicare.[15] There are two methods for a hospital to qualify for the Medicare DSH adjustment.[16] For the statutory formula, the DSH patient percentage takes into consideration the Medicare impatient days entitled to Medicaid Part A and Supplemental Security Income and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicaid Part A, For the alternate formula; large urban hospitals must demonstrate that more than 30 percent of their total net care revenues come from State and local governments for

indigent care (other than Medicaid or Medicare).[17] A DSH hospital serves a significantly high disproportionate share of low income patients.[18] DHS hospitals can be owned or operated by the State or local government, or by public or private entities which were formally granted government powers.[19] Non-hospital entities must receive federal grants and provide services to low-income or uninsured patients; however, this not a requirement for a hospital.[20] The 1992 statute indicated that the non-hospital entities that qualify under the statute are Native Hawaiian Health Centers, Tribal/Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, Black Lung Clinics and Hemophilia Centers.[21] Upon enrollment in the 340B program, covered entities must determine whether they will use 340B drugs for their Medicaid patients (carve-in) or will whether they will purchase drugs for their Medicaid patients through other mechanisms (carve-out).[22] Entities must comply with all requirements and restrictions as listed in the 340B statute.[23] A covered entity is eligible for the 340B discounted drug when it serves a qualified patient. Per the current guidance, a person is a "qualified patient" if the following criteria are met:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;

2.The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.[24]

Income is not a determining factor in a patient's eligibility.[25]

Covered entities and their affiliate sites spent over $7 billion to purchase 340B drugs in 2013, three times the amount spent in 2005.[26] In 2013, covered entities made up only 2% of $374 billion in annual drug purchases made in the U.S.[27]

HEALTH RESOURCES AND SERVICES ADMINISTRATION

HRSA was created in 1982 as a sub agency of HHS.[28] Prior to 1982; there were other agencies such as the Federal Security Agency and the Health Care Financing Administration that worked on improving the health care for needy people.[29] HRSA is the primary Federal agency for improving access to health care by strengthening the health care workforce, building healthy communities and achieving health equality.[30] As of 2015, HRSA has a $10 billion budget to support 80 different programs effecting millions of people with programs such as Health Workforce Training Programs, National Health Service Corp, Ryan White HIV/AIDS Programs and Rural Health Policy Programs to name a few. [31] HRSA also oversees or supports many other activities that are critical to the nation's health and well-being such as the national network of poison control centers, national organ transplant list, national vaccine programs as well as administering the 340B Drug Pricing Program.[32]

PHARMACEUTICAL MANUFACTURERS

In accordance with section 340B, a manufacturer who wishes to sell covered outpatient drugs to eligible entities must enter into a pricing agreement with HHS agreeing to charge a price for outpatient drugs that will be at or below the ceiling prices mandated by section 340B.[33] Failure to sell covered drugs at these prices could result in a manufacturer being prohibited from receiving payments for its products from the Medicaid program. [34] When a manufacturer launches a new product, they must estimate the 340B price and after the third quarter of sales must reconcile the difference between the estimate and actual.35 If the reconciliation indicates the entity was overcharged, the manufacturer must issue the funds to the entity regardless of the amount; however if the reconciliation shows an undercharge to the entity the manufacture is not allowed to collect the money.[36] Manufacturers are under contractual obligation to offer the mandatory 340B ceiling price discount on all covered drugs reimbursed under Medicaid to covered entities regardless of entity compliance.[37] Manufacturers are not required to provide 340B discounts to entities until they are fully enrolled in the 340B Program and listed on the OPA website.[38]

Per the OPA website as of October 26, 2015, there are 660 active manufacturers participating in the 340B drug rebate program.[39]

PHARMACIES

There are multiple types of pharmacies; however in the 340B space the pharmacies are either in-house or contract. A pharmacy is responsible for purchasing the drug from the wholesaler or on occasion directly from a pharmaceutical manufacturer and take physical possession of the drug.[40] Once the pharmacy takes possession of the drug, it is their responsibility to store it properly prior to distribute to the physician or patient.[41] It is the pharmacy that is responsible for contacting the prescribing physician if the medication prescribed is not available or not on the patients' health plan formulary.[42] If a pharmacy is part of a chain like Walgreens, CVS or Costco, the cliental that it serves can vary from uninsured, Medicaid, insured through a private carrier or patient pay.

IN-HOUSE PHARMACY

An in-house pharmacy is one that is owned by, and a legal part of, the 340B entity.[43] Typically, in-house pharmacies are listed as shipping address of the entity and the entity owns the pharmacy license.[44] Many in-house pharmacies are considered "closed-shop", which means that they only serve patients of that covered entity.[45] An in-house pharmacy located at a hospital can also dispense medications for inpatient or outpatient use. Hospital based pharmacies add an element of convenience to patients to make sure that they leave with the right medication; however, not all in house pharmacies will carry commonly used drugs like chain pharmacies.[46]

CONTRACT PHARMACY

Another type of pharmacy that services 340B patients are mostly community based off-site facilities; which are known as "contract pharmacies."[47] Covered entities may contract with multiple pharmacies, but are required to have a written contract and a full list of contract pharmacies that they work with.[48] In the case of a contract pharmacy, a "ship to bill to" procedure is used in which the covered entity purchases the drug; the manufacture/wholesaler must bill the covered entity for the drug that is purchase, but ships

the drug directly to the contract pharmacy.[49] Covered entities are responsible for ensuring that contract pharmacies are registered with the OPA.[50] Contract pharmacies may not dispense 340B drugs to Medicaid patients unless the covered entity has made arrangements with the State and the contract pharmacy to ensure no duplication of the discount.[51] Contract pharmacies must provide quarterly financial reports to the covered entity and set up and monitor a tracking system to prevent duplication of discount or diversion.[52] Per HRSA, the covered entity should complete a yearly audit of the contract pharmacy.[53]

PROHIBITIONS

The 340B statute strictly prohibits specific activities, and these prohibitions must be complied with by all covered entities that choose to participate in the 340B program.[54] The prohibitions are duplication of discount, diversion and the Group Purchasing Organization (GPO) exclusion.[55]

DUPLICATION OF DISCOUNT

Duplication of discounts is statutorily prohibited.[56] Covered entities are required to advise HRSA upon registration if they will either carve-in; use 340B drug for their Medicaid patients or carve-out; use other mechanisms to purchase drug for their Medicaid patients.[57] A National Provider Identifier (NPI) is a unique identification number for covered health care providers.[58] All covered entities must notify HRSA if they will carve-in or carve- out. For covered entities that carve-in, they must inform HRSA of their NPI, the NPI is then listed on the Medicaid exclusion file.[59] HRSA created the Medicaid exclusion file as part of their responsibility for establishing a mechanism to assure that covered entities comply with duplication of discount provision.[60] NPI numbers are used by providers to electronically submit standard transactions.[61] The OPA takes a snapshot of the exclusion list on the fifteenth day of the month prior to the start of each quarter.[62] The exclusion file is used by States and manufacturers to ensure that drugs purchased by an NPI on the list do not receive a Medicaid rebate.[63] Entities which bill Medicaid separately for covered outpatient drugs can only accept a discount for those drugs which no claims for Medicaid reimbursement were sent to the respective State Medicaid.[64] The Medicaid exclusion file is to only be used for Fee-for-Service Medicaid claims and does not apply to prevention of duplication of discount for Medicaid Managed Care claims.[65] Covered entities do not have to have the same carve-in or carve-out designation for their Fee-for-Service population as they do for their Medicaid Managed Care population.[66] Out of state covered entities present another challenge related to the exclusion file as their NPI numbers are listed under the state in which they do business.[67] Due to different reimbursement from each Medicaid state, a covered entity may decide reimbursement is more acceptable in one state over the other, yet the Medicaid exclusion file does not allow covered entities to carve-in in one state and carve-out in another.[68]

DIVERSION

Diversion of a product is when the product is sold or transferred to a patient that is not a patient of the covered entity.[69] Mixed use settings such as a hospital emergency room, infusion center or cardiac catheterization lab, or in an in house pharmacy where both inpatient and outpatient drugs are dispensed, are at higher risk for diversion.[70] The 340B program is specifically for outpatient drugs.[71] Drugs must be administered to an eligible patient of the covered entity.[72] While the 340B statute does not define

"eligible patient," HRSA has made several attempts at providing guidance to make the definition less ambiguous; however this ambiguity still leads covered entities and drug manufactures to interpret this differently.[73]

GROUP PURCHASING ORGANIZATION (GPO)

Group Purchasing Organizations (GPO's) are entities created to leverage the purchasing power of a group of members to obtain preferred pricing and/or terms on the goods and services they regularly use.[74] Hospitals and their off-site outpatient clinic sites that are registered on the OPA 340B database as participating in the 340B program are subject to the GPO prohibition and cannot purchase any covered outpatient drugs through a GPO or other group purchasing arrangement.[75] If a covered entity violates the GPO prohibition, it will be removed from the 340B Program as it will no longer be eligible for participation.[76]

PROGRAM OVERSIGHT AND MANAGEMENT

The OPA department of HRSA is charged with the responsibility to develop and administer the 340B program.[77] The OPA is responsible for ensuring compliance of the program participants, creating policies and providing guidance to covered entities and pharmaceutical manufactures.[78] HRSA requires that covered entities recertify on an annual basis in order to maintain eligibility in the program.[79] The covered entity certifies that the information listed on the OPA website such as address, contact, Medicaid exclusion status, grant status is still valid. HRSA works with drug manufactures to complete the quarterly 340B mandatory pricing.[80] The mandatory price is what a manufacture must offer to all covered entities. The OPA maintains a website which lists all of the covered entities and their eligibility status.[81] HRSA has authority to conduct audits of covered entities and manufacturers to ensure compliance of the regulations.[82] Manufacturers have the right to audit covered entities in the event they have a concern that there is duplication of discount or diversion.[83] Under the 340B law, HRSA set up a Prime Vendor Program (PVP); which is currently contracted with Apexus.[84] The Prime Vendor is responsible to negotiate prices below the mandatory 340B ceiling price and provide distribution services to covered entities that chose to access the PVP.[85] Through the PVP a website has been created to assist covered entities and manufacturers with questions about the 340B program.[86]

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010

The ACA was passed on March 23, 2010.[87] The intent of ACA was to ensure all Americans have access to quality, affordable health care and will contain health care costs.[88] In furtherance of its goals of containing raising healthcare costs, the ACA expanded the types of facilities eligible to participate in the program, and thereby enabled more providers to take advantage of the discounted drug prices.[89] The newly eligible 340B entities include critical-access hospitals, rural referral centers, sole community hospitals and freestanding cancer hospitals.[90] When the 340B program was enacted in 1992, there were 90 eligible hospitals participating in the program, this increased to 1673 by 2011, representing almost one third of the hospitals in the United States.[91] In 2012, HRSA estimated the expansion of the definition of covered entities enabled up to 1,500 new facilities to become eligible to participate in the 340B program.[92] As of 2014, there were over 28,000 providers and affiliated sites (including hospitals) participating in the program.[93] By 2019, it is estimated that the number of new Medicaid enrollees will

reach twelve million; which allows more of the new hospital entities to qualify for the 340B program.[94] Newly-eligible entities must exceed the DHS percentage for their specific type of facility, 11.75 percent for children's hospitals and free standing cancer hospitals; 8 percent for rural referral centers and sole community hospitals.[95] Accountable Care Organizations (ACOs) were also created under ACA; however an ACO itself is not a covered entity. [96] ACO's are groups of doctors, hospitals or health care organizations that voluntarily come together to provide coordinated quality care to Medicare patients.[97] Health care providers in an ACO that participates in the 340B program must continue to meet all the requirements of the 340B statute.[98] HRSA also expanded the use of contract pharmacies by covered entities in order to reach more patients.[99] Covered entities are permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition.[100] Between 2010 and 2014, the number of unique pharmacies serving as contract pharmacies increased by 154 percent.[101] The 340B ceiling price is calculated as the greater of:

Average Manufacture Price (AMP) – Medicaid Best Price discount + Price Increase % > CPI-U

Or

AMP – mandatory Medicare rebate discount + Price Increase % > CPI-U.[102]

ACA increased the mandatory Medicaid rebate discount from 15.1% to 23.1%, which increases the discounted 340B ceiling price, thus giving larger discounts to 340B entities.[103] A hospital must register all off site clinics that are going to participate in the 340B program.[104] Since the off-site clinic must be listed on the hospital cost report, only provider-based clinics can participate in the 340B program.[105] The law gives HRSA the power to enforce penalties on drug manufacturers who over charge 340B entities.[106] Manufacturers must explain how the overcharge occurred, how refunds will be calculated and whom refunds will be issued.[107]

The GAO report of 2011 showed that HRSA's oversight of the 340B report was inadequate to provide assurances that covered entities and manufactures were in compliance.[108] The GAO recommended HRSA actively audit covered entities and finalize more specific guidance.[109] Drug manufacturers have statutory right to audit covered entities; however covered entities have no audit rights of manufacturers.[110]

MEGA GUIDANCE

On August 28, 2015, HRSA issued 340B proposed omnibus or mega guidance.[111] The guidance is meant to update previous guidance's, and implements program integrity requirements under the ACA.[112] The mega guidance attempts to address the following issued: (1) Covered entity responsibilities, (2) Contract pharmacy arrangements, (3) Individuals eligible to receive 340B drugs, (4) 340B Program eligibility and registration, (5) Drugs eligible for purchase under the 340B program, (6) Manufacturer responsibilities, (7) Rebate option for AIDS Drug Assistance Programs, and (8) HHS audits of Covered Entities and manufactures and manufacturer audits of covered entities.[113]

The proposed guidance attempts clarify the current three part definition of eligible patient with the following six part test:[114]

1. 1The individual receives a health care service at a Covered Entity site which is registered for the 340BProgram and listed on the 340B public data base.

2. The individual receives a health care service from a health care provider employed by the Covered Entity or who is an independent contractor of the Covered Entity such that the Covered Entity may bill for services on behalf of the provider.

3. An individual receives a drug that is ordered or prescribed by the Covered Entity provider as a result of the service described in (2), An individual will not be considered a patient of the Covered Entity if the only health care received by the individual from the Covered Entity is the infusion of a drug or the dispensing of a drug.

4. The individual receives a health care service that is consistent with the Covered Entity's scope of grant, project or contract.

5. The individual is classified as an outpatient when the drug is ordered or prescribed.

6. The individual has a relationship with the Covered Entity such that the Covered Entity maintains access to auditable health care records which demonstrate that the Covered Entity has a provider-to-patient relationship, that the responsibility for care is with the Covered Entity, and that each element of the patient definition is met for each 340B drug.

The mega guidance proposes several responsibilities of the covered entity to ensure no duplication of discount.[115] Covered entities must continue to register with the OPA if it will carve-in or carve-out its fee-for-service Medicaid population as well as its Medicaid Managed Care population. Covered entities have the ability to make different determinations for each Medicaid population type as well as each covered entity site.[116] Changes to carve-in or carve-out can be made at any time; however they will only be effective on a quarterly basis.[117] It is assumed that if the covered entities does not list on the OPA website that their contract pharmacy will dispense 340B program drug.[118] If HRSA determines that the covered entity is not practicing in a manner stated in their actual billing practices, they would be in violation of the duplication discount prohibition and be required to pay the drug manufacture back any cost owed due to prohibition.[119] Child sites may now also contract directly with a not register or contract for pharmacy services on behalf of their individual covered entity members.[120] A contract pharmacy may be removed from the 340B program if HRSA determines that it is not complying with the 340B program requirements, and the covered entity is responsible for offering repayment to a manufacturer if a contract pharmacy has not adhered to the 340B program requirements.[121] A covered entity is expected to conduct quarterly reviews and annual independent audit of each contract pharmacy location.[122] The records of such reviews and audits are among the records that can be audited by HRSA and manufacturers.[123] Manufacturers will be required to offer a newly launched covered drug to a 340B entity as soon as available for sale.[124] Manufacturers will be required to review and update the 340B database on an annual basis.[125] Limited distribution plans must be provided to the OPA when a manufacturer uses a specialty pharmacy or restricted distribution plan or needs to limit distribution due to a potential or actual shortage.[126] Manufacturers must issue refunds to covered entities in the event that there is an overcharge by the manufacture.[127] Any refund or credit owed to a covered entity must occur within 90 days of the determination by the manufacturer or HHS that an overcharge has occurred.[128] Manufacturers would be

able to refer any other covered entity compliance issued to HHS for its review.[129] The statute does not require a manufacturer to provide reasonable cause to audit a covered entity; however the proposed guidance suggests that reasonable cause exits when a "reasonable person could conclude, based on reliable evidence, that a covered entity and/or its child sites or contract pharmacy may have violated" the duplication of discount or diversion prohibition.[130] Following an audit by HHS, a manufacturer will be provided notice of its findings to which the manufacturer has 30 days to object in writing and provide supporting documentation.[131] Upon HHS issuing its final findings, the manufacturer must submit its corrective action plan in 30 days.[132] Proposed guidance requires manufacturers to provide pharmacy; however covered entities may requested documents, not only on its own behalf, but also on behalf of "any wholesaler or organization which preforms 340B program requirements or contracts for the manufacturer".[133] HHS is authorized by statue to audit covered entities for compliance with the 340B program requirements.[134] A failure of a covered entity to correct compliance issues or submit a corrective action plan may result in termination from the 340B program.[135]

ADJUDICATION OF CLAIMS

IN-HOUSE PHARMACY

When a patient brings their prescription to the in-house pharmacy, the pharmacy must determine if the patient is a Medicaid patient or a 340B patient.[136] As stated earlier, the covered entity has to make a determination at the time of enrollment in the 340B program if it will carve-in Medicaid or carve-out.[137] This determination is how the in-house pharmacy it can be certain that at the time of dispensing the product should be dispensed under Medicaid or 340B. If the pharmacy believes that the patient is likely a 340B patient, the pharmacy will bill Medicaid using the NPI along with the 420DK "20" identifier created by NCPDP.[138] When a patient is likely not a 340B patient; then the pharmacy will bill Medicaid. During the post adjudication true up, the pharmacy reviews the prescription level data to verify the following (1) where in the facility was the patient seen? (inpatient or outpatient), (2) is the prescriber associated with the covered entity, (3) patient encounter location. After reviewing all of this information if it is confirmed the prescription was 340B than nothing is done, if it is determined that the prescription was not 340B eligible, then the in-house pharmacy must go back complete the credit/rebill process. The credit/rebill process consists of crediting the product under the 340B price and then billing Medicaid for the product.

CONTRACT PHARMACY

At a contract pharmacy, the pharmacy will review the prescription to determine if there is insurance coverage, which can be private insurance or Medicaid.[139] Once the pharmacy determines the insurance coverage, they bill the insurance and the patient pays any required co-payment.[140] Contract pharmacies often do not know at the time of dispensing if the drug is to a patient that meets the eligibility requirements under the 340B statute.[141] To assist in identifying 340B purchases, covered entities hire third party administrators to do post adjudication of the prescriptions filled at the contract pharmacy.[142] The administrator will review (1) the dispense date of the prescription, (2) prescriber, (3) product dispensed, (4) patient name.[143] If any of the claims are determined not eligible, then the contract pharmacy must credit and re-bill the ineligible claims. Instead of keeping physical inventories, many

contract pharmacies use a replenishment model.[144] Replenishment occurs when a non-340B drug is initially dispensed to a 340B eligible patient, and a contract pharmacy later replaces the non-340B dispensed drug with 340B purchased inventory.[145] The replaced inventory, although it was purchased at 340B prices, is no longer considered 340B inventory as the title passes to the pharmacy after purchase.[146]

CURRENT ENFORCEMENT AND OVERSIGHT

In 2011, the GAO reported that HRSA's oversight of the 340B program is lacking.[147] The GAO reported found that HRSA expects participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and to inform HRSA of any violations.[148] HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others 'compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with intent.[149] For example, the 340B statute required HRSA to set up a mechanism to prevent duplication of discount, thus the Medicaid Exclusion file was created; however it is not required that each State Medicaid use the file to compare against the data received from the pharmacy.[150] The fact that use of the Medicaid Exclusion file is not mandatory leaves the covered entity at risk that the pharmacy billed claims incorrectly and leaves the pharmaceutical manufacturer at risk for duplication of discounts paid through Medicaid. States such as Oregon and Texas have setup their own internal process on how a pharmacy should bill a Medicaid claim in order to prevent duplication of discount.[151] Currently there is no mechanism in place to prevent duplication of discount on Medicaid Managed Care utilization that since 2010 is eligible for Medicaid Rebates.[152] The current patient definition is not specific enough leaving covered entities to determine the eligibility of a patient.[153] Due to this, covered entities are either interpreting very narrow, thus potentially forgoing a 340B discount or too broad, thus potentially leading to diversion.[154] The report goes on to say that operating the 340B in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies.[155] For example, contract pharmacies are more likely to serve both patients of covered entities and other in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverts – intentionally or unintentionally – to non-340B patients.[156] In 2014, the Office of Inspector General Evaluations and Inspections department completed another review of contract pharmacy arrangements in the 340B program.[157] The report found that there was still an issue with contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways.[158]

Per the 340B statute, HRSA has always had the ability to audit covered entities and manufacturers; however it was not until the passage of the ACA that HRSA really began to perform routine audits.[159] HRSA's recent audits of covered entities have found instances of duplicate discounts and diversion related to contract pharmacies.[160] Since 2010, the unique number of pharmacies serving as 340B contract pharmacies has grown 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent.[161] In 2014, of 32 entities that HRSA had audited, 10 were cited for diversion and/or duplicate discounts through contract pharmacies.[162] As of October 29, 2015, for fiscal year 2015, HRSA has done 122 audits of covered entities with 40 findings of un- registered contract pharmacies, diversion and/or duplicate discounts through a contract pharmacies and only one audit of a pharmaceutical

manufacture; which resulted in no findings.[163] Currently there is a question of whether HRSA has the authority to make rules under the 340B program. On July 23, 2013, HHS promulgated a final rule about Orphan Drugs; which was challenged by Pharmaceutical Research and Manufacturers of America (PhRMA) and vacated.[164] The 2013 rule indicated that specific hospitals were excluded from buying orphan drugs under 340B to treat the rare disease or condition for which the drug received the orphan designation; however they were allowed to purchase orphan drugs at 340B pricing when used to treat other conditions or diseases.[165] The court went on to say "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program" and the statutory provisions HHS relied on as authority to promulgate the rule were "specific grants of authority that do not authorize the orphan drug rule."[166] Instead, the Court noted that Congress granted HHS only "a specific delegation of rulemaking authority to establish an adjudication procedure to resolve disputes between covered entities and manufacturers." [167] On July 21, 2014 HHS release an interpretive rule stipulating that orphan drugs can be purchased under 340B for indications other than the orphan designation; which was also challenged by PhRMA and vacated on October 25, 2015.[168] PhRMA challenged the interpretive rule indicating that it had the same meaning and effect as the final rule that was vacated by the court.[169]

RECOMMENDATIONS FOR GREATER OVERSIGHT

While the proposed Mega Guidance issued in August 2015 attempts to clarify many challenges in the 340B program, it does not address how to prevent the violations of duplicate discounts and diversion found in the HRSA audits. 340B Health indicated that 59% of the audits done in 2015 have found issues of duplication and diversion.[170]As much of the health care industry has regulations and oversight, there is a desperate need to create and enforce greater oversight in the 340B Program. While the expansion in the use of contract pharmacy arrangements has been beneficial for patients, it has jeopardized covered entities abilities to remain compliant with the statute. Guidelines are needed on what should be required in a contract between a covered entity and a contract pharmacy. Since covered entities bear the burden of making sure that their contract pharmacies are compliant, they should be required to complete routine audits. If a covered entity and/or a contract pharmacy is found to be non-compliant via a self audit, manufacturer audit or HRSA audit the following should occur (1) the findings should be disclosed on the OPA website, (2) all manufacturers should receive letters disclosing the non-compliance, (3) all refunds due should be resolved within one year and (4) HRSA should be required to verify with all parties that the refunds have been paid. Contract pharmacies should be subject to audit by manufacturers and HRSA. Since many contract pharmacies are part of a chain, when there a findings from a covered entity involving a chain contract pharmacy, HRSA should audit the entire contract pharmacy chain as it is likely that all locations are using the same adjudication system. Each covered entity should be required to have their name and address on the prescription pad or be noted on an electronic prescription. This will assist in reducing the potential of duplicate discounts being submitted under multiple covered entities for providers that work at more than one covered entity. Covered entities should disclose to the contract pharmacy if they carve in or carve out. Covered entities that elect to carve out should be prohibited from allowing their contract pharmacy from dispensing drug under 340B. Contract pharmacy adjudication systems should be updated with flags to indicate which covered entity the prescription originated from in order to identity if the claim should be billed under Medicaid or 340B. Covered entities should ensure that contract pharmacy adjudication systems are audited on a quarterly basis. Since HRSA created the Medicaid exclusion file in accordance with the statute, all states should be required to use it.[171] However

since Medicaid is a program administered by the Center for Medicaid and Medicare Services (CMS), it is CMS that would need to enforce that all states use the file. This is just one of the cross over challenges between Medicaid and 340B that require HRSA and CMS to collaborate to ensure compliance in both programs.

CONCLUSION

It appears that while HRSA/OPA is responsible for oversight of the 340B Program, HRSA's ability to make rules and enforce them is limited. These limitations go beyond the authority in which Congress has bestowed, but also to the financial and staffing resources that are needed. While the OPA's budget has been increased since the 2010 expansion of the 340B program; its abilities to understand all of the inconsistencies and compliance challenges of the program will take time and education.172 In this current economic environment, the notion of allowing the participants to self-police themselves has been less than effective; which has been proven by the 2011 GAO and 2014 OIG reports as well as the HRSA audits. With over 800 comments submitted in response to the 2015 Mega Guidance, neither covered entities nor pharmaceutical manufacturers feel that all of the challenges of the program have been addressed or are fairly applied across the participants.173 Contract pharmacies have been a discussion of concern since HRSA expanded the use in 2010. In 2013, Congress has expressed concern to HRSA about the complexity and challenges of the contract pharmacy arrangements.174 A 340B inventory analyst for Walgreens, the leader in contract pharmacy arrangements, noted on social media that Walgreens was set to increase their revenue due to the contract pharmacy explosion.175 This comment prompted Senator Grassley wrote a letter to Walgreens asking for detailed information on how they run their 340B contract pharmacy arrangements.176 With so much attention placed on the contract pharmacy arrangements, it shocking that the Mega Guidance did not address concerns expressed by Congress. If Congress intends to fix this program, they must grant authority to HRSA to make rules that all participants must follow and not interpretive guidance that will be left to the participants' discretion. It is necessary for the appropriate authorities to review the 340B program and determine the program currently works to achieve the goals that it was intended to meet.

References

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[3] Pub.L. 101–508, 104 Stat. 1388, enacted November 5, 1990.

[4] Office of Inspector General, OEI 12-90-00800, *Strategies To Reduce Medicaid Drug Expenditures*, at

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[8] § 602; PHS Act § 340B; 42 U.S.C. § 256b.

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