TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	4,000	200,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					290,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

Dated: January 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–331 Filed 1–11–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 340B of the Public Health Service Act implements a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. The purpose of this notice is to inform interested parties of proposed guidelines regarding contract pharmacy services that will allow covered entities to utilize contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project program.

DATES: The public is invited to comment on the proposed guidelines by March 13, 2007. After consideration of the submitted comments, the Health Resources and Services Administration (HRSA) will issue the final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

A. Background

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act, Limitation on Prices of Drugs Purchased by Covered Entities. Previous guidelines pertaining to contract pharmacy services for the 340B drug pricing program (61 FR 43549, Aug. 23, 1996) stated that a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services.

In 2001, HRSA established Alternative Methods Demonstration Projects (AMDPs) which allowed covered entities that applied and were approved by HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included the following: (1) The use of multiple contract pharmacy service sites, (2) the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or (3) the development of a network of 340B covered entities. The intent was to allow community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients. From the time of the program's inception until the end of April 2006, a total of 18 AMDPs were approved. Of those, 11 utilize a multiple contract pharmacies model, four establish a network of 340B covered entities, one is a combination of the network model and the multiple contract pharmacies model, one utilizes a contract pharmacy to supplement an in-house pharmacy, and one utilizes multiple contract pharmacies to supplement an in-house pharmacy. All but one of the projects is currently ongoing. A condition of AMDP approval is the requirement that the approved demonstration project be audited annually by an independent, outside auditor for drug diversion and duplicative discounts under Medicaid. The results of the audits are required to be reported to the Office of Pharmacy Affairs (OPA). To date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program.

HRSA, acting through OPA, is proposing new guidelines that would allow covered entities to utilize multiple contract pharmacy service sites and the utilization of a contract pharmacy to supplement in-house pharmacy services that were previously limited to approved AMDPs. This proposed change is due to the success of the AMDPs, and the urging of safety net providers who wish to utilize alternatives to the single entity site/single pharmacy location contractor model to provide broader access to 340B discounted drugs to eligible patient populations. Other than permitting these specified models, HRSA is not proposing other substantive changes to the contract pharmacy guidelines. The AMDP process will continue for those covered entities wishing to develop 340B networks of covered entities. OPA will continue to review the utilization of network demonstration projects and consider adapting the rules to include them in the future. Of particular importance is the continued requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute.

These proposed guidelines replace all sections of previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services,'' 61 FR

43549 and any individual correspondence issued by HRSA on the subject. Demonstration projects previously approved under the multiple contract pharmacy model, the supplement to in-house pharmacy model, or a combination of the two models when this Federal guidance goes into effect, would be governed by this guidance and would no longer be subject to expiration of AMDPs, interim reporting or annual audits currently mandatory for all demonstration projects (this guidance only applies to audits required under the AMDP and leaves unchanged audit requirements under any other authority or program). While annual audits will no longer be required to be provided to OPA annually, covered entities are required to maintain fully auditable records and OPA expects covered entities to include appropriate sampling of multiple contract pharmacy arrangements in the course of routine annual audits. Demonstration projects previously approved to utilize the network model would continue to be subject to all program requirements and conditions set up under the AMDP. Any covered entity wishing to utilize a network model would still be required to seek approval under the AMDP and may not do so without formal approval.

B. Contract Pharmacy Services Mechanism

(1) Basic Requirements for Utilization of Contract Pharmacy Arrangements

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between themselves and a pharmacy. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate ''in-house'' pharmacy services, those covered entities who have access to ''in-house'' pharmacy services but who wish to supplement these ''in-house'' services, and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: ensure against illegal diversion and duplicate discounts, maintain readily auditable records, and meet all other 340B Drug Pricing Program requirements. OPA has provided a model agreement format below as guidance for the type of contractual provisions expected in such agreements as well as suggested contract provisions in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (4) below.

(2) Potential Alternatives to Single Location, Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures meeting the basic requirements outlined in (1) above between the covered entity and each pharmacy; (b) the operation continues to meet all 340B Drug Pricing Program requirements and does not create unlawful diversion or duplicate discounts; and (c) the arrangements are one of the two following models individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy (ies) to supplement in-house pharmacy services. The use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy location. Supplementing in-house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site seeks to purchase drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location.

(3) Model Agreement Provisions

The following are suggested provisions for a model agreement:

(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of a HHS grant (if applicable) and any applicable state and local laws and consumer protection laws.

A ''ship to, bill to'' procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy (Section 1 of Appendix.) In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The contract pharmacy will provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice.

(c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than a covered entity's contract pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to only patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all HHS grantees, disproportionate share hospitals and FQHC Look-Alikes will adhere to all rules and regulations that apply to them as grantees or otherwise eligible entities.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. *See* 42 U.S.C. 256a(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the Office of Pharmacy Affairs by the covered entity.

(j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C § 256a(a)(5).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, the Department, and the manufacturer in the case of an audit.

(k) Upon written request to the covered entity, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential or proprietary information may be deleted from the document.

(4) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the entity directs the drug shipment to its contract pharmacy(ies), we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide OPA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is required to submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy(ies) containing the aforementioned provisions (see 3 above). However, if a covered entity wishes to utilize an agreement with provisions different from those listed above that it believes meets 340B requirements; OPA will review the proposed agreement provisions for sufficiency. The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing, the names and 340B identification numbers of all covered entities participating, and the names of any pharmacies participating.

(5) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contract pharmacies and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contract pharmacy in return for the contract pharmacy or an entity owned or controlled by the contract pharmacy agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contract pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, or the remodeling of the covered entity's premises. For example, if a contract pharmacy agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contract pharmacy to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contract pharmacy agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contract pharmacy for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as ''safe harbors.'' These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which must be met in order for a person or entity to be immune from prosecution or exclusion under the safe harbors.

C. Appendix—Suggested Contract Provisions

(1) ''The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy).''

(2) ''The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will

ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.''

(3) ''Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.''

(4) ''The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer.''

Dated: December 22, 2006.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient''

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted Section 340B of the Public Health Service (PHS) Act ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that in order to obtain Medicaid reimbursement for its covered outpatient drugs, a manufacturer must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price to covered entities for outpatient drugs that will not exceed an amount determined under a statutory formula. Section 340B is administered as the ''340B Drug Pricing Program'' and is commonly referred to as ''the 340B Program.''

Section 340B states that it is illegal for covered entities to sell medications purchased under the 340B Program to persons who are not considered ''patients'' of the covered entity. The purpose of this notice is to inform interested parties of proposed clarifications to the definition of ''patient'' for whom the covered entity can purchase discounted pharmaceuticals under the 340B Program. This clarification is necessary to protect the integrity of the 340B Program and to assist covered entities and other participants in their compliance efforts.

DATES: The public is invited to submit comments on the proposed guidelines by March 13, 2007. After consideration of the comments submitted, the Secretary will issue final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

Introduction

Section 340B(a)(4) of the PHS Act and section 1927(a) of the Social Security Act list the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. Eligibility for participation in the 340B Program is strictly limited to the specific categories of entities specified in these statutes.

Section 340B(a)(5)(B) of the PHS Act prohibits entities from selling (or otherwise transferring) drugs purchased under the 340B Program to anyone who is not a patient of the covered entity. Responsibility for ensuring compliance with this provision rests with the covered entity. Congress did not define the term ''patient'' in Section 340B, and initial HRSA guidelines implementing the 340B Program directed covered entities to ''develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount'' in order to prevent diversion. To accomplish this, entities were encouraged to utilize a separate purchasing account and separate dispensing records (See 59 FR 25110).

As covered entities, manufacturers, and others began to implement the 340B Program, it became apparent that additional clarification of the patient definition was needed and on October 24, 1996, HRSA issued additional guidelines regarding the definition of a covered entity ''patient'' (61 FR 55156). These guidelines stated that the following definition of patient would apply for the purposes of the 340B Program:

An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

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

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*