businesses and organizations receiving grants from HHS; *Total Number of Respondents:* 25; *Frequency of Response:* monthly; *Average Burden per Response:* 15 minutes; *Estimated Annual Burden:* 75 hours.

The PMS–272, Federal Cash Transactions Report, is used to monitor Federal cash advances to grantees and obtain Federal cash disbursement data. It serves in place of the SF–272. *Respondents:* State and local governments, profit and nonprofit businesses and institutions receiving grants from HHS; *Total Number of Respondents:* 11,050; *Frequency of Response:* Quarterly; *Average Burden per Response:* 4 hours; *Estimated Annual Burden:* 176,800 hours.

Total Burden: 176,875 hours.

Send comments to Douglas F. Mortl, PSC Reports Clearance Officer, Room 17A08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 19, 1996.

Lynnda M. Regan,

Director, Program Support Center.

[FR Doc. 96–21530 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–17–M

Health Resources and Services Administration

RIN 0905–ZA96

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992'' (the ''Act''), enacted section 340B of the Public Health Service Act (''PHS Act''), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of final guidelines regarding contract pharmacy services.

FOR FURTHER INFORMATION CONTACT: Annette Byrne, R. Ph., M.S., Director, Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594–4353, FAX (301) 594–4982.

EFFECTIVE DATE: August 23, 1996.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed guidelines for contract pharmacy services were announced in the Federal Register at 60 FR 55586 on November 1, 1995. A comment period of 30 days was established to allow interested parties to submit comments. The Health Resources and Services Administration, Bureau of Primary Health Care, acting through the Office of Drug Pricing (ODP), received eleven letters including comments concerning the scope of the 340B Program, contractor certification, contractor and entity penalties for drug diversion, creation of an agency relationship between the entity and the contractor, entity responsibilities including price establishment, reimbursement, inventory control, and the like.

Although some manufacturers expressed concerns regarding the potential for drug diversion, the Department has received no evidence of diversion that has required an official Departmental investigation. This includes the various drug distribution systems, among them those using contract pharmacy services. However, in response to manufacturers' concerns, the Department intends to study the use of contracted pharmacy services for accessing 340B drugs to determine if there is evidence of drug diversion. In particular, the Department will examine closely documented complaints, including the results of manufacturers' audits, will use other analyses as deemed appropriate, and will consider whether additional safeguards are necessary.

We received some very positive comments in support of the mechanism. These comments discussed the many covered entities which do not operate their own licensed pharmacies; therefore, the guidelines encourage these entities to participate in the program. Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies. One commenter described the guidelines as straightforward, clear and consistent with section 340B. Another commenter stated that the ''use of contract pharmacies by covered entities is fundamental to the success of the VHCA [Veterans Health Care Act] drug pricing program.'' The commenter supported the guidelines and urged the Department to expedite their completion, as the importance of the contract pharmacy option to their members could not be overstated.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice, with changes made to increase clarity and readability. In addition, to provide further technical assistance and guidance to covered entities interested in using this mechanism, examples of report contents, a suggested system to ensure an adequate drug tracking system, and a method to ensure patient eligibility are included. Various commenters, and in particular drug manufacturers, suggested the need for detailed systems. The National Association of Community Health Centers suggested some of the specific examples.

(B) Comments and Responses

(1) General

Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS Act and results in an unauthorized expansion of the program.

Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.

It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, 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.

During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

As early as 1993, several covered entity groups and a home care company came forward to assist the Department in developing a workable mechanism to use outside pharmacies under arrangements which would decrease the drug diversion potential. The result was the November 1 proposed notice, which articulates a voluntary model agreement. Currently, contract pharmacies are used by a number of large organizations, such as the American Red Cross, several community health centers, and the New York Blood Consortium.

It must be understood that the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility. However, it has permitted more eligible entities to participate in the program with a reasonable assurance that the potential for drug diversion is eliminated.

Comment: The guidelines were proposed without a comprehensive notice and comment period.

Response: During the early months following enactment, it became clear that there were many gaps in the legislation and some form of program structure was necessary to move the program forward. There were approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal programs affected by this legislation and all seeking guidance. It was incumbent upon the Department to implement this difficult Congressional mandate in an expeditious manner.

Interpretive rules and statements of policy were developed to provide necessary program guidance. The Department has published these guidelines in the Federal Register, used a Federal clearance process (including the Office of Management and Budget's clearance) and provided a public comment period to obtain both Federal as well as public input into guideline development. The Department considered all comments in developing these final guidelines.

The guidelines explain how the Department intends to administer the 340B, further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties; therefore, they are not subject to the Administrative Procedure Act's requirement of notice and comment. Nevertheless, the Department chose to solicit and respond to public comment.

Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs. By issuing guidelines in this area, ODP is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.

Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Comment: Participation in the contract pharmacy mechanism by hemophilia treatment centers funded under the Maternal and Child Health Block Grant Program would contravene the central goals of that program and could result in grant termination or non-renewal.

Response: Block grant funds are designed for formula allocation to the States to meet specific defined needs in the legislation. Congress recognized that the Maternal and Child Health Bureau (MCHB) had other needs that should be met more flexibly; therefore, fifteen percent of the appropriation is a discretionary set-aside. These funds are not subject to the specific parameters of block grant funds but instead are used to fulfill other goals within the MCHB mission. This includes the provision of services (including pharmaceuticals) to individuals with hemophilia disorders and their families. Therefore, the purchase of pharmaceuticals by hemophilia centers does not contravene grant principles.

Comment: The contract pharmacy mechanism contravenes Federal and State laws and regulations (e.g., Prescription Drug Marketing Act and the Anti-kickback Statute).

Response: We found no indication that the guidelines contravene Federal or State law. Regarding allegations that the guidelines contravene the Prescription Drug Marketing Act (PDMA), it is clear that the guidelines fall squarely within the PDMA resale exception that allows the dispensing of a prescription drug purchased by a health care entity when dispensing is pursuant to a prescription. See 21 U.S.C. 353(c)(3)(B)(v). Under the guidelines, the contract pharmacy would dispense 340B drugs to patients of the covered entity pursuant to a prescription. The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy. Moreover, the guidelines include controls intended to prevent diversion and provide for accountability of drug stocks. For these reasons, the guidelines are consistent with both the letter and the spirit of the PDMA.

We believe it necessary to ensure that covered entities contracting with pharmacies to dispense 340B drugs are aware of the requirements of the Federal anti-kickback statute and the way in

which such requirements could apply to their arrangements with contracting pharmacies. To this end, we inserted into the guidelines a discussion of the statute's requirements and its potential application in this type of contracting situation.

In addition, provision (e) of the guidelines provides that the ''contractor and the covered entity will adhere to all Federal, State, and local laws and requirements.'' As a general matter, we found it impossible to discuss each State's laws and regulations regarding drug purchase, distribution, and dispensing in relation to the many different types of entities and their individual needs. We believe it appropriate that the guidelines include a provision that requires each entity and contractor to be responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations.

Comment: The ODP should develop a uniform contractual agreement and distribute this agreement to covered entities for use without modification.

Response: The guidelines propose a model format only. The Department has included in the guidelines provisions necessary to ensure that covered entities and contract pharmacies understand and agree not to violate 340B provisions. Because of the wide diversity of covered entities (including hemophilia clinics, large hospitals, migrant health clinics, family planning service programs and State AIDS drug assistance programs), it would be impossible to include provisions responsive to the needs of all entities.

Comment: ODP should keep a list of all acceptable contract pharmacies.

Response: Any pharmacy licensed by a State Board of Pharmacy is acceptable.

Comment: Some State laws require that manufacturers ensure that a buyer is licensed to purchase pharmaceuticals. Covered entities that do not have pharmacy operations would not be licensed, and thus, in some States, manufacturers could not receive from the covered entity the assurance required by State law.

Response: Provision (e) provides that the covered entity will adhere to all Federal, State and local laws and requirements. Accordingly, if State X requires an entity to be licensed to purchase drugs and a covered entity subject to the laws of State X does not have a pharmacy license, it may not be able to purchase drugs. However, if State X permits a covered entity to use contract pharmacy services to purchase drugs on its behalf, the entity could presumably use this mechanism. To the extent the guidelines may be inconsistent with a State's distributor licensing requirements, this same reasoning would apply.

Comment: Covered entities may bill insurers for 340B drugs at the usual price, resulting in the savings not being passed on to the patients.

Response: Section 340B does not limit the pricing behavior of covered entities. It is our understanding that covered entities have a variety of drug pricing approaches. While some may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost plus a reasonable dispensing fee, using the savings to reach more eligible patients and provide more comprehensive services. The Department intends to examine the section 340B drug pricing activities of covered entities to determine the various approaches used and the rationale for these approaches. However, until it completes its examination of this issue, the Department notes that a modest section 340B price markup, with saving realized from the discounts used by covered entities only for purposes of the federal program (including certain disproportionate share hospitals) which provides its section 340B eligibility does not appear to be inconsistent with the drug pricing program.

Comment: There should be a limitation to only those covered entities that do not have the capability under State pharmacy law to purchase and dispense prescription drugs.

Response: The guidelines have been revised to read that the ''mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to an appropriate 'in-house' pharmacy services.'' However, this is not a bar to the use of the mechanism by any covered entity.

Comment: A covered entity should use only one form of participation, and if it purchases in its own right for some patients, it should not use a contractor for others.

Response: Some covered entities may receive nominal pricing directly from a manufacturer (e.g., family planning) for specific drugs, may obtain certain drugs through promotional discounts, or have a manufacturer-specific indigent free drug program which could necessitate the procurement of other pharmaceuticals from a retail pharmacy. The statute does not limit the covered entities' access to these avenues of drug purchasing.

Comment: The Department should establish criteria that a contractor and a covered entity must meet in order to be in compliance with section 340B provisions and receive 340B pricing.

Response: The contracted pharmacy mechanism does establish these criteria in that it includes provisions for purchasing only by the entity and not contractor, identifies customary and adequate records that can provide an audit trail, preclusion of the filling of Medicaid prescriptions (thus preventing duplicate discounting), and three provisions related to the potential for drug diversion (agreement not to divert with specified penalties, customary drug tracking systems, and an agreement to permit manufacturer and HHS audits).

Comment: The reference to ''facility'' in provision (b) should be changed to ''entity'' for clarification.

Response: The guidelines were revised accordingly.

Comment: The Department should review all contracts between covered entities and pharmacies or develop a procedure for certifying that each contract pharmacy arrangement meets the mechanism criteria.

Response: The Department has added a provision to the guidelines which suggests that covered entities utilizing contract pharmacy services submit to the ODP a certification that they have signed and have in effect an agreement with the pharmacy contractor containing provisions (a) through (k) as outlined in the guidelines. For the convenience of participating drug manufacturers, the names of covered entities which submit a certification, or have submitted an alternate mechanism to reduce the potential for drug diversion which has been approved by ODP, will be placed on the program electronic bulletin board (EDRS) for public access.

Comment: Covered entities should be permitted to contract with more than one site and contractor. Although we understand that the limitation of one contractor (with multiple sites) was intended to address drug diversion concerns, covered entities will have the incentive of directing their patients to the contract pharmacy site participating in the program, even though there may be several nonparticipating sites of contractors that would be more convenient for the patients.

Response: Covered entities are unlikely to select a contract pharmacy that is not convenient for their patients. See also the discussion of patient choice, below.

Comment: PHS is moving from a direct purchase discount program to an indirect charge-back contracting system.

Response: All 340B drugs will be sold to covered entities; therefore, there are no additional charge backs involved.

(2) Patient Choice

Comment: Provision (c) provides that the patient may obtain the prescription from the pharmacy provider of his or her choice. Pharmacy providers cannot provide prescriptions, as only a physician can write a prescription. The guidelines should permit the patient to obtain the prescription from the covered entity physician and then be able to fill that prescription at the pharmacy of his or her choice. Further, the covered entity physician should inform each patient that he or she has the freedom to choose any pharmacy to fill the prescription.

Response: The use of the word ''prescription'' may be somewhat confusing. We have revised this provision to read ''may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.'' In addition, a provision is added to address the responsibility of the covered entity physician to inform the patient of his or her freedom of choice.

Comment: Wording should be added to provision (c) to make it clear that when a patient obtains a drug from a retail pharmacy other than the entity's contract pharmacy, the manufacturer does not have to offer this drug at 340B pricing.

Response: The guidelines were revised accordingly.

(3) Bill to/Ship to

Comment: The type of ''bill to, ship to'' arrangement proposed in the notice is not a ''purchase'' by the covered entity.

Response: Please note provision (a) of the notice which states ''the covered entity will purchase the drug.'' The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity.

Comment: A ''ship to, bill to'' arrangement may not be lawful in many States (e.g., state distributor licensing requirements).

Response: The Department obtained information from both the American Pharmaceutical Association and the National Association of Boards of Pharmacy which suggests that no State would consider this type of activity unlawful.

Comment: If the ''ship to, bill to'' procedure is implemented through wholesalers, there are no procedures in place that can enable a manufacturer to conduct an adequate audit.

Response: The guidelines provide that the covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. These records will be maintained for the period of time required by the State law and regulations. The guidelines provide that the contractor will provide the covered entity with reports consistent with normal business practices as well as maintain records separate from it's own operation. In addition, the contractor will agree to be subject to audits by both the manufacturers and the Department. In light of these provisions, audits will be possible, regardless of whether drugs are shipped by manufacturers or wholesalers.

Comment: A ''ship to, bill to'' procedure could interfere with marketing arrangements that an individual manufacturer may have established as part of its usual business practices.

Response: Because the manufacturer is still selling to the covered entities, we can see no interference with marketing arrangements. The manufacturer will be using its usual business practices. Only the delivery of the drug will be altered.

Comment: The covered entity (not its contractor) will place all orders for drugs based upon its projections of the needs of its patients.

Response: Because the covered entity will have no knowledge of the inventory levels of the pharmacy, it would be unrealistic to include a provision that the covered entity will order 340B drugs.

Comment: The covered entity, consistent with customary business practices in wholesale purchases, should make timely payment of invoices for drugs shipped to the contractor pursuant to the entity's order.

Response: We have included this concept in the guidelines, Section 1 of Appendix.

(4) Penalties

Comment: The penalty for the contract pharmacy which violates the agreement not to resell or transfer a drug purchased at 340B pricing is inadequate. Knowing violators should be fined beyond their unjust profit and criminal and fraud penalties should be imposed.

Response: The Department has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent the Department is aware that improper action by an entity or a contract pharmacy may be a violation of law, we will refer such cases to appropriate authorities.

(5) Potential Drug Diversion

Comment: PHS should conduct an annual audit of each contract pharmacy to ensure compliance with all Departmental rules and regulations.

Response: Subject to the availability of funds, the Department intends to conduct a study of the contract pharmacy mechanism. Depending upon the results of this analysis and the availability of funds, further study may result. Annual audits of each contract pharmacy situation would be burdensome and are not feasible.

Comment: Contract pharmacies will be motivated to identify patients other than those of the covered entity whose drug usage can afford the contractor a profit opportunity. The covered entity should be responsible to the manufacturer for any diversion by the contractor of 340B drugs to individuals who are not patients of the covered entity.

Response: The guidelines contains provision (h), in which both parties agree to not ''resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity.'' In addition, this provision provides that if diversion has occurred, the contractor will pay the amount of the discount in question so that the covered entity can reimburse the manufacturer, as required by section 340B(a)(5)(D).

Comment: The mechanism should include provisions for ensuring that the agreement will, in fact, be enforced.

Response: The Department does have the authority to remove a covered entity from the eligibility list if it (or its contract pharmacy) is found to have diverted 340B drugs to individuals who are not patients of the entity. To this end, the Department has developed a mechanism to receive and investigate complaints concerning drug diversion. This mechanism was published in the Federal Register for notice and comment on June 10, 1994 (59 FR 30021). In addition, the Department, at various public meetings concerning the implementation of 340B, has requested documentation of any covered entity drug diversion. To date, the Department has received no indication of drug diversion in relation to drugs purchased at 340B discount pricing that has required an official Departmental investigation.

Comment: The manufacturer appears to bear the sole risk arising from abuses of the program and has no recourse if such abuse occurs. The manufacturer

has limited ability to verify an arrangement between the covered entity and the contract pharmacy. Under the statute, the manufacturer's only remedy is to demand an audit; however, the lack of final audit guidelines has effectively prevented manufacturers from undertaking this type of activity. PHS should make arrangements for injunctive relief to prevent damages from ongoing violations of the statute, or provisions for terminating the participation of covered entities or their contractors.

Response: The manufacturer has sufficient remedies available to detect and eliminate abuse of the program. First, the manufacturer may audit the entity. Although the audit guidelines were not published in final form, we consider the proposed guidelines, published in the Federal Register, a sufficient statement of Department guidelines to allow manufacturers to proceed with an entity audit. Second, the Department has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that is in violation of 340B. Third, the contract pharmacy guidelines provide that if the covered entity or its contractor is found to have violated the 340B prohibition against drug diversion (and duplicate discounting), the covered entity could be removed from the list of covered entities and could no longer access 340B pricing.

Comment: The covered entity should establish a process for a quarterly reconciliation of its prescribing records with the contractor's inventory and dispensing records to provide for early detection of diversion and remediation of irregularities.

Response: We have included a provision that covered entity will establish a process for a quarterly random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities.

Comment: The covered entity should establish prior authorization protocol, assuring that the individual's status as a patient of the entity is confirmed by the entity in advance of product dispensing.

Response: The contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program. To that end, we have added a provision to the guidelines stating that the covered entity and the contractor will develop a system to verify patient eligibility (e.g., eligible patient list or a validated prescription). Additionally, we have included a suggested contract provision which states, ''(pharmacy) will dispense covered drugs only in the following circumstances: (1) 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, and the signature of a legally qualified health care provider affiliated with the (covered entity); or (2) receipt of a prescription ordered by telephone 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) should provide a list to the (pharmacy) of all such qualified health care providers and will update the list of providers to reflect any changes, which is consistent with customary business practice.''

Comment: The contract agreement should restrict pharmacy services to only those patients who receive their medical care from the covered entity.

Response: Provision (g) of the guidelines provides that the contractor will not resell or transfer a 340B drug to an individual who is not a patient of the entity. The Department issued proposed guidelines to define the word ''patient'' in a Federal Register notice on August 3, 1995. See 60 FR 39762. Provision (2) of the definition provides that an individual is a patient of a covered entity if, among other requirements, 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 the responsibility for the care provided remains with the covered entity.'' Currently, the Department is analyzing the comments received in response to that notice and is developing final guidelines.

It must be noted that the covered entity is responsible for any diversion of its drugs to ineligible individuals; therefore, it must make every effort to thoroughly scrutinize the contractor's dispensing records, to determine if the 340B drugs were dispensed to only eligible recipients. If a manufacturer believes that a covered entity contractor is diverting 340B drugs to ineligible recipients, the manufacturer should immediately contact the Department with this information and submit all supporting documentation so that a thorough investigation can be initiated.

Comment: PHS should oversee contractors' compliance with the contracts regarding the 340B prohibition against drug diversion and duplicate discounting.

Response: Because the covered entity purchases the drug, retaining title, and directs shipment to its contractor, it retains responsibility for the drug. If the drug generates a Medicaid rebate or is diverted to an individual who is not a patient of the covered entity, the entity will be responsible for such activity. The Department and a participating manufacturer have the authority to audit the records of the covered entity and the contractor that directly relate to that manufacturer's drugs and to the 340B prohibitions against drug diversion and duplicate discounting. See proposed Audit Guidelines, 59 FR 30021, June 10, 1994. Further, the Department has proposed a dispute resolution process in which a manufacturer may bring a claim against an entity for drug diversion or duplicate discounting. See Dispute Resolution, 59 FR 30023. If the entity (or its contractor) is found to have violated such prohibitions, the entity is required by 340B(a)(5)(D) to pay the manufacturer the amount of the discount in dispute, and, pursuant to 340B(a)(4), the Department may determine that the entity is no longer a ''covered entity'' eligible to access 340B pricing.

We have added several suggested contract provisions that are consistent with normal business practices to the guidelines (Appendix) to provide further technical assistance in this area. One provision concerning potential discrepancies in ordering and shipping states, ''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.'' Concerning an appropriate tracking system to prevent drug diversion, another provision states, ''prior to the 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 and may require (the pharmacy) to make any modifications to such system as the (covered entity) may, in its sole discretion, require. Such a system may include sample quarterly comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records. The (pharmacy) will permit the (covered entity) or its duly authorized representatives to have reasonable access to (pharmacy's) facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. (Pharmacy) agrees to

make any and all adjustments to the tracking system which (covered entity) advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the (covered entity).''

Comment: There should be a process for excluding from the 340B Program those contractors that are in violation of the statute and the guidelines should explicitly note that the pharmacy contractor will be subject to additional civil or criminal penalties if violation of the guideline involves a violation of State or Federal law.

Response: Covered entities which are found to have violated the prohibitions of section 340B(a)(5) can be excluded from the 340B Program, after an appropriate opportunity to be heard. See Dispute Resolution Guidelines in 59 FR 30023, June 10, 1994. However, if the program finds that the pharmacy contractor has violated these statutory prohibitions, it cannot bar this pharmacy from dispensing 340B drugs for a covered entity. Nevertheless, the program intends to alert any entity which submits a certification with this particular pharmacy listed as the contractor as to this pharmacy's past activities. If the covered entity insists upon using this pharmacy, the Department will carefully scrutinize its activities. An additional provision was added to address the potential for civil or criminal penalties if the contractor violates Federal or State law.

Comment: The agreement should appoint the pharmacy contractor to be the agent of the covered entity and discuss the duties to be performed by the agent on behalf of the covered entity and the agent's rights.

Response: We believe that the relationship between the covered entity and the contract pharmacy is one of agency. However, the form of the relationship will be dictated by the terms of the contract; therefore, it is not essential to characterize the relationship as meeting or not meeting the standards which would serve under applicable law to establish an agency relationship. The contract terms address the relative duties of the parties in relation to section 340B and diversion and duplicate discount concerns that have been raised by the commenters. Accordingly, we have concluded that it is unnecessary to label the relationship between the covered entity and the contract pharmacy.

Comment: The contract pharmacy is fully accountable for maintaining the security of the PHS inventory.

Response: There is no requirement for a separate (physical) inventory for drugs purchased at a 340B discount, because a separate data system will be used to verify appropriate dispensing.

Comment: Contract pharmacies are most likely Medicaid pharmacy providers, while the covered entity likely is not. Because State Medicaid programs are unlikely to issue pharmacy numbers to anyone other than licensed pharmacies, covered entities that are not licensed pharmacies will not be able to bill Medicaid for prescriptions dispensed by the contract pharmacies. This task will be completed by the contract pharmacy. The mechanism excludes Medicaid drugs; therefore, the contract pharmacy must have two Medicaid numbers (i.e., 340B exclusion package and one to bill Medicaid for its regular customers). However, PHS has not required the contract pharmacy to do so. Moreover, neither the pharmacy nor the State has any incentive to ''make arrangements'' to carry out the statute, since both may gain from inadequate enforcement.

Response: The mechanism requires the parties to comply with the prohibition on filling Medicaid prescriptions with drugs purchased at 340B pricing. Neither the covered entity nor the contract pharmacy will bill Medicaid for 340B drug reimbursement; therefore, there will be no need for two Medicaid numbers. The 340B drugs will not generate Medicaid rebates.

Comment: As the owner of the drug, the covered entity should be responsible for establishing the price for each drug sold to a patient of the entity (effectively preventing the contractor from charging whatever price it chooses) and assuming full responsibility for such prices under the terms of the PHS grant and any applicable consumer protection laws.

Response: Even though it is clearly stated in the guidelines that the covered entity must purchase the drug (not the contractor), which would give to the covered entity title to and responsibility for the drug, we have added the following clarifying language to provision (a): ''* * * will purchase the drug and will assume full responsibility for establishing its price, pursuant to terms of a PHS grant (if applicable) and any applicable consumer protection laws.''

(6) Records

Comment: The contractor should assure that all pertinent reimbursement accounts and dispensing records maintained by the contractor for the covered entity are separate from the contractor's own operations and are accessible to the covered entity, PHS, and the manufacturers in the event of an audit. The contractor should provide these records to the manufacturer upon request.

Response: We have added the concept of separate records to provision (j) to assure the availability of these records in the case of an audit by the manufacturer. However, a manufacturer has statutory authority to access these entity records by performing an audit; therefore, to require the entity to submit records upon demand would be unduly burdensome.

Comment: ODP should establish standards for reporting that will ensure consistency of the information and approve whatever ''record-keeping'' system is used.

Response: Any reasonable system which will provide an adequate audit trail will be acceptable. However, reporting should be consistent with State pharmacy laws and other reporting mechanisms. As stated earlier in this section, sample contract provisions are suggested which describe such records and reports (e.g., prescription files, velocity reports, and records of ordering and receipt).

Comment: Reporting requirements should include some record or report that assures that only patients of the covered entity were served.

Response: Provision (f) provides that the contractor will provide the covered entity with reports as deemed appropriate using normal and customary business records.

Comment: The agreement should require that the pharmacy contractor maintain separate inventories and separate records for patients of the PHS entity contracting for pharmacy services.

Response: The guidelines have been changed to include a provision for separate dispensing records for patients of the covered entity. However, the requirement for a separate inventory of 340B drugs is unnecessary, because the covered entity is required to monitor dispensing and inventory records. In addition, these records are also subject to Department and manufacturer audits. A separate inventory is a wasteful concept with respect to time, space and money. Further, it provides little if any additional security, as a separate inventory only speaks to what is currently on the shelf and not what should be on the shelf. On the other hand, dispensing and other records will accurately indicate use of 340B drugs.

Comment: The covered entity is responsible for making arrangements to seek reimbursement from third parties for 340B drugs used in treating patients of the entity. If the covered entity receives a PHS grant, it would lose its

grant eligibility for failing to make appropriate arrangements.

Response: Since the entity purchases the drugs, it has the option of seeking reimbursement from third parties itself or contracting for this service. However, to the extent that a covered entity (or its contract pharmacy acting on its behalf) fails to comply with grant conditions, the entity may be subject to grant penalties.

Comment: To the extent that the covered entity makes arrangements for the pharmacy contractor to submit claims for third party reimbursement, the covered entity should assume full responsibility under State consumer protection laws, insurance, fraud, and State and Federal health care laws with respect to any false claims charges or allegations of consumer or insurance fraud.

Response: The ODP is not authorized to enforce or interpret such laws. If we become aware of possible violations of such laws, we will refer these cases to appropriate authorities.

(C) Contract Pharmacy Services Revised Final Mechanism

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy. This mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to appropriate ''in-house'' pharmacy services. *See* Appendix for suggested contract provisions.

(1) The following is a suggested model agreement format:

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

A ''ship to, bill to'' procedure may be used in which the covered entity purchases the drug, the manufacturer bills the entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. *See* section 1 of Appendix.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The ODP will be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor.]

(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 the entity contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing.

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

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

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 contractor 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 contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted 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 random (sample) comparison of its prescribing records with the contractor'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. [The Department's draft guidance defining covered entity ''patient'' is set forth in an August 3, l995, Federal Register notice. See 60 FR 39762.]

Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(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, a 340B(a)(5) prohibition, and no longer be eligible for 340B pricing. See Section 4 of Appendix.

(i) Both parties will not use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounting.

(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 Medicaid rebates and 340B discounts. See section 340B(a)(5).

The contractor will assure that all pertinent reimbursement accounts and dispensing records, maintained by the contractor, will be separate from the contractor's own operations and will be accessible to the covered entity, the Department, and the manufacturer in the case of a manufacturer audit.

(k) Upon request, 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 propriety information may be deleted from the document.

(2) Certification

Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, 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 duplicating discounting.

To provide ODP and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is encouraged to submit to ODP a certification that it has signed and has in effect an agreement with the contract pharmacy containing the aforementioned provisions. However, ODP will review any alternative mechanism which is designed to reduce the potential for drug diversion. The names of those covered entities which submit a certification, or an alternate mechanism approved by ODP, will be placed on the EDRS for the convenience of participating drug manufacturers.

(3) Anti-kickback Statute

Contractors and covered entities must be aware of the potential for civil or criminal penalties if the contractor violates Federal or State law. In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors 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 contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor 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 contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor 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 may be met in order for a person or entity to be immune from prosecution or exclusion.

(D) Appendix—Suggested Contract Provisions

(1) ''The covered entity will order covered drugs directly from the manufacturer, from a designated sales representative, or a drug wholesaler and arrange to be billed directly for such drugs. The covered entity will arrange for shipment of such drugs directly to the pharmacy. 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) pursuant to the entity's order.''

(2) ''The covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act 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 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 pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to 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 pharmacy agrees to make any and all adjustments to the tracking system which 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, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone 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 pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.''

Dated: August 14, 1996.

Thomas G. Morford,

Acting Administrator, Health Resources and Services Administration.

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National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request the Framingham Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on the proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: The Framingham Study. Type of Information Collection Request: Extension of a currently approved collection (OMB No. 0925–0216). Need and Use of Information Collection: This project involves physical examination and testing of the surviving members of the original Framingham Study cohort and the surviving members of the offspring cohort. Investigators will contact doctors, hospitals, and nursing homes to ascertain participants' cardiovascular events occurring outside the study clinic. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. Frequency of Response: The cohort participants respond every two years; the offspring participants respond every four years. Affected Public: Individuals or households; Businesses or other for profit; Small businesses or