

republished in its entirety; and amended on September 28, 2009 to provide targeted liability protections for pandemic countermeasures to enhance distribution and to add provisions consistent with other declarations and republished in its entirety. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F–2(b)(4) of the Act.

X. Definitions

For the purpose of this Declaration, including any claim for loss brought in accordance with section 319F–3 of the PHS Act against any covered persons defined in the Act or this Declaration, the following definitions will be used:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: Means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, Tribal, State, or Federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.

Covered Persons: As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms “manufacturer,” “distributor,” “program planner,” and “qualified person” are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic influenza A viruses and those with pandemic potential: Animal and/or human influenza A viruses, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, that are

circulating in wild birds and/or domestic animals, that cause, or have significant potential to cause, sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naïve.

Pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Pre-pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas.

Dated: February 26, 2010.

Kathleen Sebelius,
Secretary.

APPENDIX

I. List of U.S. Government Contracts—Covered H5N1, H2, H6, H7, H9, and 2009–H1N1 Vaccine Contracts

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI–0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C
32. All present, completed and future Government H5N1, H2, H6, H7, H9, and 2009–H1N1 vaccine contracts not

otherwise listed.

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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: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the “Veterans Health Care Act of 1992” enacted Section 340B of the Public Health Service Act (PHS). Section 340B implements a drug pricing program by which manufacturers who sell covered outpatient drugs to particular covered entities listed in the statute must agree to charge a price that will not exceed the amount determined under a statutory formula. The purpose of this Final Notice is to inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies and suggested contract pharmacy provisions, which had been previously limited to the Alternative Methods Demonstration Project program.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, Maryland 20857 or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

DATES: *Effective Date:* April 5, 2010.

SUPPLEMENTARY INFORMATION:

A. Background

Proposed guidelines for contract pharmacy services were announced in the **Federal Register** at 72 FR 1540 on January 12, 2007. A comment period of 60 days was established to allow interested parties to submit comments. HRSA, HSB, acting through the OPA, received 32 comments concerning the proposal.

In 1996, HRSA issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity’s patients (61 FR 43549, August 23, 1996). Those guidelines permitted a covered entity to use a single point for pharmacy services, either an in-house pharmacy or an

individual contract pharmacy. Since 2001, covered entities that have wanted to use other types of arrangements, or to blend the method of providing services (e.g. contract pharmacy to supplement an in-house pharmacy) have needed to apply to the OPA for an Alternative Methods Demonstration Project (AMDP) and secure approval in order to proceed.

It is important for all covered entities to keep in mind that use of a contract pharmacy arrangement (single, multiple or AMDP) does not lessen a covered entity's duty to ensure that the 340B program is being administered in compliance with the statute and HRSA guidelines. The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid Rebate claim. Covered entities will be 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. Auditable records must be maintained to demonstrate compliance with those requirements. Such records must be maintained for as long as required by Federal, State and local law.

Additionally, compliance with 340B requirements and guidelines does not excuse individual providers, covered entities, pharmacies, wholesale distributors or manufacturers from adherence to all other local, State or Federal requirements.

Covered entities should also be mindful that use of a contract pharmacy is voluntary. Covered entities are not required to use multiple contract pharmacies or any contract pharmacy at all. Each covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services.

We received many comments in support of the proposal. Many of these came from covered entities that participate in 340B and highlighted how their delivery of patient care would be enhanced with a multiple contract pharmacy option. According to these comments, some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. This would permit covered

entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served.

Comments raised a number of issues: Audits; protecting against diversion; network models; limits on the number or location of contract pharmacies; and the need for model agreement provisions and certification procedures. Also addressed was the potential impact on manufacturers, pharmacies, covered entities and patients. Additional comments challenged the sufficiency of the data used to justify the changes, and questioned whether the proposed notice was in compliance with the Administrative Procedure Act.

The following section presents a summary of all major comments, grouped by subject, and a response to each grouping. All comments were considered in developing this Final Notice, and changes were made accordingly. Other changes were made to improve clarity and readability.

B. Comments and Responses

(1) Administrative Procedure Act (APA) Compliance

Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.

Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA. Nonetheless, HRSA has published these guidelines in the **Federal Register** and provided a public comment period to obtain input into guideline development. The present guidelines used this same process. HRSA has considered all comments, both Federal and public, in developing the Final Guidelines.

Comment: Eleven demonstration projects out of a total of 12,000 covered entities do not give HRSA enough data to expand the scope of the contract pharmacy model. An additional demonstration project, with not less than 100 sites, should be the next step

to further evaluate risks and benefits of the expanded model.

Response: At the time of publication of the proposed guidance there had been 18 demonstration projects. HRSA realizes that only a small percentage of covered entities have gone through the AMDP process. HRSA is working with the data that exists, which was overwhelmingly supportive of the guidelines. Although there have been a limited number of AMDPs approved, some of the approved projects included a large number of health care sites and contract pharmacies. The number of participating health care sites exceeded 50 and the number of contract pharmacy sites was over 170. The results of the AMDP are not the only basis for issuing this guidance. The circumstances surrounding pharmacy practice and the resources available to track transactions have changed substantially over the past decade. The AMDP provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity. Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site. The restriction has imposed its own costs by restricting the flexibility of covered entities in meeting the needs of their patients. Furthermore, pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion. The use of multiple contract pharmacies is not appropriate for all covered entities; however, we do not find a blanket restriction on all covered entities to be justified.

(2) Audits

Many commenters presented varying perspectives on the topic of audits. Multiple comments from drug manufacturers argued that manufacturers should be given the ability to audit covered entities that use multiple pharmacy contracting services due to the heightened risk of drug diversion and duplicate discounts. Other comments focused on HRSA audit requirements, arguing that they should be identical to the current standards required for the AMDP. Finally, some comments supported not having an audit requirement, arguing that audits would be burdensome and costly for the covered entities.

Comment: The audit requirements from the AMDP process should be applied to multiple contract pharmacies. There is no evidence of diversion and duplicate discounts

because of the audit requirements. Their elimination may lead to increased diversion and duplicate discounts. Some commenters recommended retaining the audit requirements for at least a few years until a track record of compliance with multiple contract pharmacies can be created. Audits should include a full compliance review of all mandatory contract terms/requirements including implementation of tracking system, patient status verification, and providing information about other pharmacy options.

Response: Although HRSA does not believe that precisely the same procedures are appropriate as utilized under the AMDP, HRSA agrees that independent audits can play an important role in ensuring program integrity. The guidelines have been revised to state that the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the recognition of any problem. Furthermore, the guidelines have been revised to indicate that it is the expectation of HRSA that covered entities will fulfill their ongoing obligation by the utilization of independent audits. However, HRSA leaves it up to covered entities to determine how to meet their compliance responsibilities. The guidelines intentionally do not specify the precise method, personnel or items for ensuring sufficient information is obtained by the covered entity. As long as covered entities comply with their obligations under the guidelines, HRSA prefers to leave the method of compliance to the judgment of the covered entities.

To the extent that any internal compliance activity or audit performed by a covered entity indicates that there has been a violation of 340B program requirements, it is HRSA's expectation that such finding be disclosed to HRSA along with the covered entity's plan to address the violation.

Comment: A copy of the audits conducted by covered entities should be submitted to OPA. The results of such audit should be made available to manufacturers.

Response: HRSA does not feel there is a need for the automatic submission of audits conducted by covered entities. HRSA believes that there are already appropriate safeguards in place. Covered entities are required to maintain auditable records sufficient to demonstrate continued compliance with 340B requirements; and, to the extent that a situation warrants, HRSA will request copies of any internal compliance documents of covered entities.

Comment: Covered entities should be required to conduct audits of their contract pharmacies and be required to terminate the contract with pharmacies found to be in violation.

Response: As noted earlier, HRSA agrees that audits can play an important role in ensuring integrity, and that covered entities are required to have sufficient information to ensure against diversion and duplicate discounts. The extent to which an audit of the contract pharmacy or other arrangement is necessary to satisfy that obligation will depend upon the individual circumstances. Covered entities have the responsibility to have agreements with contract pharmacies and procedures in place sufficient to enable the covered entity to meet its obligations under the law, including the prohibition on diversion and duplicate discounts. While an audit capability and various grounds for termination are terms that could be included in such contracts, there is no requirement in the guidelines for such terms. However, covered entities are reminded that they retain ultimate responsibility for compliance with the 340B program. Covered entities may be well-served by ensuring that compliance terms are included in their pharmacy contracts. To the extent that covered entities uncover these problems, the appropriate response is to report those problems to HRSA and ensure that they are properly addressed.

Comment: Manufacturers should be permitted to audit covered entities that use multiple contract pharmacy services. No reasonable cause should be required, due to heightened risk of diversion.

Response: We do not agree that utilization of more than one contract pharmacy creates automatic cause to suspect diversion. The issue as to whether additional audits by an outside manufacturer are permitted is addressed in the guidance published in the **Federal Register** on that issue (61 FR 65406, December 12, 1996). To the extent a manufacturer believes there is a reasonable basis to conclude that a covered entity is in breach of program requirements, it may audit a covered entity consistent with these guidelines. Additionally, HRSA has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that are in violation of 340B. For further guidance on the audit and dispute resolution process see 61 FR 65406 (December 12, 1996). As indicated in this guidance, covered entities and contract pharmacies must retain auditable records of 340B covered

drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients and against duplicate discounts.

Comment: It would be burdensome for covered entities to provide reports and data for audits. It is unclear who would be required to construct the actual components of the audit, what would be included, and who would pay for it.

Response: HRSA would like to remind all 340B stakeholders that it is an option for covered entities to voluntarily enter into contract pharmacy arrangements. Each covered entity is encouraged to conduct its own analysis of the costs and benefits of implementing or expanding their pharmacy services. It is the responsibility of the covered entity to ensure against diversion and duplicate discounts. Covered entities may determine how to best meet that responsibility: By performing a separate audit, including spot audits as part of pre-existing auditing responsibilities, or via other mechanisms. HRSA believes that including these issues as part of an independent audit is the best but not necessarily the only approach to meet covered entities' ongoing responsibility to know that their covered outpatient drugs are being appropriately ordered and distributed to their patients.

(3) Diversion

Comment: The proposed guidelines do not adequately describe safeguards that will combat drug diversion and duplicate discounts. There should be more severe penalties for violations, especially duplicate discounts.

Reimbursement of any inappropriate discounts is insufficient and will not deter bad behavior. A covered entity should be excluded from 340B if it continues to use a pharmacy found to be in violation of the program.

Response: HRSA believes that there are appropriate safeguards in place, based on the parameters of the program. HRSA has the ability to exclude covered entities that abuse the program. HRSA has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent HRSA is aware that an action by a covered entity or contract pharmacy may be a violation of the law, such cases are referred to appropriate authorities.

Comment: The proposed guidance appears to limit the need to segregate records for easy accessibility by auditors rather than for purposes related to ensuring there is no diversion. Is this intended, or is segregation, virtual or

otherwise, still expected to be used by the contract pharmacy as a method of showing that diversion has not occurred?

Response: All covered entities are required to have auditable records sufficient to fully demonstrate compliance with all 340B requirements. Any covered entity that chooses to utilize a contract pharmacy must ensure that any such contract fully addresses that requirement and has the responsibility to ensure that the contract is actually performed and administered in compliance with those requirements. Inventory and record segregation is one of many methods that can be used to ensure compliance with the program guidelines. HRSA does not intend to limit the methods covered entities may use in order to remain in compliance with the guidelines. As noted previously, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients as well as duplicate discounts.

Comment: Covered entities should be required to maintain and provide to HRSA and manufacturers written policies and procedures for preventing diversion and duplicate discounts in their contract pharmacy services.

Response: The ultimate responsibility for compliance with all aspects of the 340B program lies with each covered entity. The contract arrangements between covered entities and outside pharmacies will have various terms and procedures, which are acceptable as long as there are no violations of the program. It is expected that all covered entities will have written policies and procedures for preventing diversion and duplicate discounts as part of their obligations to prevent diversion and duplicate discounts. They are also required to maintain auditable records. HRSA will not automatically require covered entities to submit such policies and procedures for HRSA review.

(4) Contract Pharmacy Services Mechanism—Potential Alternatives to Single Location/Single Pharmacy Model

Comment: HRSA should permit separate covered entity sites to enter into one comprehensive agreement between the sites and a single contract pharmacy, instead of requiring a separate agreement for each site. Additionally, HRSA should permit a covered entity to enter into one comprehensive agreement with a chain pharmacy binding on multiple locations of the chain, instead of requiring a

separate agreement for each contract pharmacy site.

Response: Each covered entity retains its own responsibility for compliance with the program. With respect to a covered entity with multiple sites, HRSA agrees that a single covered entity may contract for sites that are integral parts of the covered entity and for which it has legal control of so long as all of the requirements are met in the contract. This approach maintains and recognizes the central responsibility of the covered entity. In the case of agreements with “chain pharmacies,” there appears to be potential for loss of accountability without a clearly established relationship between the actual pharmacy site and the covered entity. Covered entities are not precluded from entering into agreements with chain pharmacies, however, each participating pharmacy location must be listed on the contract and comply with the requirements.

Comment: One comment suggested that HRSA should clarify the definition of “multiple.” The commenter interprets “multiple” to mean that an FQHC could contract with more than one pharmacy, including more than one site of a chain pharmacy, more than one independent pharmacy, or a combination of chain sites and independent pharmacies. Additionally, the commenter interprets “multiple” to mean that a covered entity with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy. The commenter encourages OPA to adopt this interpretation in the final guidance.

Response: HRSA agrees with the comment about the meaning of “multiple” and believes that the Final Notice is clear with respect to this meaning.

Comment: Does a covered entity that currently has an agreement with only one contract pharmacy need to revise its agreement with that pharmacy if the entity subsequently enters into agreements with additional pharmacies?

Response: The covered entity may need to revise its existing contract, depending on the terms that it contains. There is no requirement in the guidelines to revise contracts, as long as they meet the criteria outlined. All entities are encouraged to seek competent counsel to assess their needs.

Comment: The proposed guidelines do not provide cautionary language about possible negative results of implementing a multiple contract pharmacy model. Some small pharmacies that currently contract with covered entities may be hurt by implementation of the guidance due to

reduced business. More guidance and decision analysis tools should be provided to guide the process of deciding whether to implement.

Response: HRSA notes that participation in any multiple contract pharmacy models is completely voluntary. All stakeholders are encouraged to conduct a full business analysis to determine whether to implement a multiple contract pharmacy model before moving forward. HRSA also provides free technical assistance for covered entities, including assistance with business analysis, to help navigate these issues. Ultimately, the decisions and responsibility for those decisions lies with the covered entity.

(5) Network Models

Comment: Multiple commenters proposed that network arrangements (*i.e.* arrangements involving a network of more than one covered entity) should be permitted under the guidelines without prior approval from HRSA. They argued that network arrangements would decrease the burden on covered entities and contract pharmacies by simplifying the contracting process and maintaining multiple inventory records. They also made the point that networks would also encourage parties to participate in 340B and therefore, expand access to eligible patients.

Response: HRSA understands the comments that a network model might potentially ease the administrative burden for participants in some cases. However, due to ongoing concerns about maintaining the integrity of the program with such complex arrangements, at this time, we decline to include network models in the guidelines without the added scrutiny of the AMDP process. HRSA will reassess the appropriateness of the utilization of networks outside the AMDP process as sufficient experience with them is gained in the future.

Comment: Some comments urged HRSA not to permit networks of multiple covered entities outside the framework of the AMDP process and requested confirmation that under the new guidance the development of a network of 340B covered entities will remain subject to the entire process now applicable to the AMDPs.

Response: HRSA agrees that covered entity networks should remain under the AMDP process, as indicated in the response to the prior comment.

Comment: “All covered entities participating” language is unclear. Does it mean a covered entity with multiple sites, a network model, or a DSH would need to name each covered entity that

has an agreement with a pharmacy under contract with the covered entity? If so, that would be burdensome on the entity, which would need to research and identify other covered entities that may contract with a particular pharmacy. What is the justification for requiring a covered entity to specify the names and 340B ID numbers of other participating covered entities?

Response: If a covered entity wants to use any alternative to a single location/single pharmacy model, it must submit its name and 340B identification number, and the names of all participating pharmacies to HRSA. Network models will still need to go through the AMDP process. The commenter is correct that the "all covered entities participating" language is unclear, because such arrangements only apply to a single covered entity. The language has been changed in response to this comment.

Comment: The guidelines should limit the numbers and geographical locations (not over State lines) for contract pharmacy relationships. Perhaps contract pharmacies should only be added one at a time. Monitoring various sites by the covered entity may be extremely difficult unless safeguards are in place.

Response: HRSA understands the commenter's concerns, but at this point, HRSA declines to limit the number of arrangements, as long as each arrangement meets our guidelines. Each covered entity retains the obligation to ensure its program remains compliant with the guidelines. HRSA does not intend to prescribe the methods covered entities use to run their programs or to ensure compliance at this time. Each covered entity and contract pharmacy is responsible for ensuring that its particular contracting arrangements and operations conform to the requirements of all applicable Federal, State and local laws and regulations.

(6) Model Agreement Provisions/ Covered Entity Compliance Elements

In the final guidelines the phrase "Model Agreement Provisions" has been changed to "Covered Entity Compliance Elements" to better reflect the purpose of the elements and to distinguish them from model contract provisions.

Comment: Covered entities with multiple contract pharmacy arrangements should have written contracts with each pharmacy, including procedures to ensure against drug diversion and duplicate discounts, to maintain records available for audit, and to meet all other 340B requirements. Covered entities should

submit these contracts and procedures to HRSA.

Response: HRSA agrees in part, which is why the guidelines do require a covered entity to have a contract that specifies all participating pharmacy locations. Such contracts must include adequate terms to ensure compliance with all aspects of the 340B program as listed in the Covered Entity Compliance Elements. However, at this time, HRSA does not have the need, or the resources to collect and review each contract. The covered entity bears responsibility for compliance with the program and will be held accountable in the event of non-compliance.

Comment: HRSA should create a single list of model contract terms, add suggested language on duplicate discount prohibition, and require covered entities to certify that their contracts use these terms or apply to HRSA for approval to use alternative terms.

Response: The Appendix of the guidelines does include a list of suggested contract provisions. HRSA has included 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, it would be impossible to include provisions that would respond to the needs of all covered entities.

Comment: Manufacturers should be allowed to request copies of the contracts between the covered entities and contract pharmacies.

Response: Manufacturers are certainly permitted to request copies of such contracts, however, HRSA declines to mandate that covered entities must provide copies of contracts upon any request. In the event a manufacturer demonstrates a reasonable need for the copy of a contract and its request for a copy of the contract has been denied, the manufacturer may ask OPA to obtain a copy. The suggested Covered Entity Compliance Elements include providing a copy of the contract pharmacy service agreement upon the request of the Office of Pharmacy Affairs.

Comment: The Appendix provisions impose additional requirements not discussed in Section (3) of the proposed guidance and the suggested provisions in Section (3) do not appear in the Appendix. The Appendix does not mention the 340B prohibition on duplicate discounts.

Response: The Suggested Contract Provisions, found in the Appendix of the Guidelines, are not meant to be comprehensive, exhaustive, or required. They offer a model format and sample provisions, but are not intended to be

used as the complete terms of the contract.

Comment: Covered entities should not be permitted to use alternative mechanisms other than the model agreement provisions. The use of alternatives would increase OPA's oversight responsibilities, which may lead to different standards or the potential for abuse. A commenter also cited GAO/OIG reports on lack of oversight of the program to support his/her assertion that the model provisions should be required.

Response: The Covered Entity Compliance Elements are not intended to be required contract provisions. All covered entities must certify that all of the elements have been addressed; however, HRSA gives the covered entities the discretion to negotiate contract provisions suitable to their individual circumstances and jurisdictions. The various complexities of covered entities and the pharmacies with whom they will contract led HRSA to permit flexibility between the parties in designing their contract terms. HRSA does not intend to review contracts. As under the previous guidelines, the covered entity is ultimately responsible for assuring full compliance with 340B.

HRSA disagrees with the comment that recent reports by the GAO and the OIG would support the creation of a standard uniform contract. HRSA has worked diligently to implement the recommendations of both the GAO and the OIG, and HRSA does not believe that dictating to covered entities specific contract language that must be used in all contracts regardless of individual circumstances would assist in those efforts at this time.

(7) Miscellaneous Comments

Comment: Anti-kickback provisions may prohibit pharmacies from offering Medication Therapy Management and Pharmacy by Mail activities that would be beneficial to 340B and patients.

Response: Covered entities are not exempt from anti-kickback provisions. Section 340B does not authorize HRSA to grant any exceptions whether beneficial or not. It is recommended that covered entities get competent professional legal advice when appropriate.

Comment: In section B(3)(c), the proposal states that the manufacturer is not required to offer the 340B drug price if the patient declines to use the contract pharmacy. If however, the manufacturer does extend the 340B price in this case, please clarify whether this extension sets a new best price for the drug.

Response: The 340B drug pricing program does not restrict the prices that manufacturers voluntarily choose to offer to patients outside the parameters of the program. Whether such actions serve to set a new best price for a drug is beyond the scope of this guidance. We encourage anyone with specific best price questions to consult with the Centers for Medicare & Medicaid Services.

Comment: To prevent drug diversion, an additional contract requirement should be added that the contract pharmacy may not fill or refill a prescription using 340B medications until the covered entity confirms that the individual is a patient of the entity at the time the prescription is filled. There should also be an independent, annual audit to review the covered entity's policies and procedures for patient verification.

Response: The program guidelines for 340B make it clear that only individuals who are patients of the covered entity are eligible for drugs purchased under the program. Like all other program requirements, responsibility for compliance lies with the covered entity, which must structure agreements and systems appropriately to ensure that diversion does not occur. Technical assistance may be available for help with implementation and compliance for the 340B program, and maximizing the value of comprehensive pharmacy services for their patients. However, HRSA has chosen not to require time-of-services verification as suggested in the comment.

Comment: Pharmacy records from contract pharmacies should be made available to covered entities to ensure patient safety and continuity of care.

Response: HRSA agrees that this might be beneficial for patient care and encourages the parties to include such terms in their contract agreements. However, this is a decision which will be left to the contracting parties. In any case, the covered entity must have sufficient records or direct access to records for the covered entity to meet its responsibility to ensure compliance and to provide a complete audit trail to verify that there is no diversion or duplicate discounts.

Comment: HRSA should include in its final guidance and suggested contract provisions, language to reinforce that all savings from the 340B program should remain with the covered entity. Without written guidance, all savings will not be returned to the covered entity.

Response: HRSA agrees that the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the

program was intended to accrue to the covered entities. However, the covered entity is free to negotiate how it chooses to use any such funds as it sees fit. For example, the covered entity is free to choose to use those dollars to pay contract pharmacies for their services or for extra services such as delivery.

C. Contract Pharmacy Services Mechanism

These final guidelines replace all 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.

(1) Basic Compliance Issues in Utilization of Pharmacy Services Contracts

A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy. A single covered entity that has more than one 340B eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract. 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 that have access to "in-house" pharmacy services but wish to supplement these 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 (*See: <http://www.hrsa.gov/opa/introduction.htm>*). HRSA has provided essential covered entity compliance elements below as guidance for the type of contractual provisions expected in such agreements. Suggested contract provisions are also in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (5) 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 that meet the requirements outlined above in (1) between the covered entity and each pharmacy; (b) the written agreement includes, and fully addresses, all of the essential elements outlined in (3) and (4) below and a full listing of all pharmacy locations that may be utilized under that agreement; (c) the operation under the contract continues to meet all 340B Drug Pricing Program requirements and does not create diversion of covered drugs or duplicate discounts; (d) the arrangements are one of the two following models either 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 purchases drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location; and (e) the arrangement involves a single identifiable 340B covered entity and does not include a network, or other similar arrangement, of more than one covered entity unless specifically authorized in writing by HRSA through an AMDP or by other official written authorization.

(3) Essential Covered Entity Compliance Elements

The following are essential elements to address in contract pharmacy arrangements: (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 an HHS grant (if applicable) and any applicable Federal, State and local 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. *See* 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 agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (*e.g.*,

dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy (ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or "in-house."

(c) The covered entity 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 pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house 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 or its patients 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 patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates 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 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. The system should be subject to modification in the event of change in such 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. 256b(a)(5)(B). The covered entity understands that it may 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 OPA, HRSA, by the covered entity.

(j) The covered entity and contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.

(k) Both parties understand that they are subject to audits by outside parties (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. 256b(a)(5)(c).

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, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

(l) Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

(4) Ongoing Responsibility of Covered Entity To Ensure Compliance

Covered entities are responsible for ensuring that the system of distribution chosen fully meets statutory obligations of ensuring against diversion to non-

patients or creating a situation that results in a State Medicaid Program seeking a rebate on a discounted drug. The covered entity remains responsible at all times for the disposition of covered outpatient drugs it purchases through a contract pharmacy. Annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected, although the exact method of ensuring compliance is left up to the covered entity. The covered entity must have sufficient information to ensure it is meeting that responsibility.

Independent audits are particularly valuable where the covered entity utilizes multiple pharmacy options. They should follow standard business practices for audits, including audit trails provided by the entity to the auditor, and use of standard reports. The precise methodology utilized to ensure compliance and obtain the necessary information is up to the covered entity given its particular circumstances and, for example, might include spot audits where the system in place permits. Drug diversion and duplicate discounts are a significant concern of HRSA and all efforts to avoid these problems should be well documented. In the event a covered entity determines that drug diversion or duplicate discounts have occurred or that it is otherwise unable to comply with its responsibility to reasonably ensure compliance, then it must take immediate remedial action to assure compliance and notify the OPA about such compliance problems and actions taken to remedy those problems.

(5) 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 covered entity directs the drug shipment to its contract pharmacy or pharmacies, the covered entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide HRSA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, covered entities should submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy or pharmacies that satisfies both (3) and (4) above (i.e. that the contract(s) fully address the issues listed in (3) and that the covered entity has a

plan to meet its ongoing responsibilities to ensure compliance). 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 and the names of any pharmacies participating when registering. Covered entities seeking to materially change this arrangement that entail changes in the covered entity database should notify OPA of any such proposed changes and be aware that some changes may require advanced notice to manufacturers and wholesalers as part of quarterly updates to the database.

In order to ensure accuracy, integrity and transparency, the OPA may conduct a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements. It is currently expected that the annual process would include certification by a duly authorized official: (1) That all information listed on the database for that covered entity is complete, accurate, and correct; (2) that the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so; (3) that any contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements; and (4) the methodology utilized to ensure compliance (e.g. through independent audit or other mechanism).

(6) *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).

D. Appendix—Suggested Contract Provisions

The following suggested contract provisions are included for illustrative

purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for

consideration, but are not intended to be used as the complete terms of the contract. Given the variances among many jurisdictions and among the numerous types of covered entities, HRSA has decided at this time not to include a complete model contract in this notice.

(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 prescribers and will update the list of prescribers 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: March 2, 2010.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-3070 and CMS-416]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency’s function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*