

INFORMATION REQUIRED FOR THE APPROVAL OF AN ALTERNATIVE METHOD DEMONSTRATION PROJECT

The following criteria are used to evaluate Alternative Methods Demonstration Project (AMDP) proposals. This information may be useful in developing a proposal for a covered entity as a guide, it is not a template.

1. Need

The main purpose of AMDP is to increase access to 340B priced pharmaceuticals. Describe in depth why current methods of utilizing the 340B program are not adequate. Examples:

- a. Inconvenient hours of operation for current pharmacy site
- b. Wide geographic expanse of patients served
- c. High administrative costs
- d. Pharmacy services for 340B covered entities currently do not exist

The proposal should also include a detailed description of need for the demonstration project. This can be shown through demographic data, current access data or with the use of maps. Examples:

- a. Map of site and / or pharmacy locations – showing proximity
- b. Description of area served
- c. Demographic description of patients served. Examples:
 - i. Poverty status
 - ii. Insurance status (i.e. % uninsured)
 - iii. Population of target area
 - iv. Number of prescriptions dispensed
 - v. Noncompliance rates
 - vi. Notable prevalence of disease in area served
- d. Most importantly, justify statements of need with data.

2. Description of the Method

Describe in as much detail, what the participants plan to do and how it will be accomplished.

3. Methods of Evaluation

In order to make a decision about the overall success of the demonstration projects, the Office of Pharmacy Affairs (OPA) will rely on approved sites to provide reliable data so that an appropriate decision can be made in the future on including these practices into the 340B guidelines.

Please provide valid and reliable methods of evaluation to determine effectiveness of the proposal to improve access to drug therapy and comprehensive pharmacy services for the uninsured or underserved patients of the covered entity.

These reports should document progress by addressing the following topics:

1. Evaluate the impact of the project on improving access to prescription drugs.
2. Explain actions to reduce administrative costs and expand access to prescription drugs.
3. Evaluate procedures to prevent drug diversion and Medicaid rebates on drugs purchased at 340B prices.
4. Demonstrate the value of participating in the 340B program in order to make these medications available to greater numbers of network patients.

Other important areas to address: additional costs incurred as a result of the demonstration project, how those costs are being defrayed or funded, cost/benefit ratios, number of medications ordered, and number of patients being served. The inclusion of best practices, keys to success, or helpful hints for other health centers that may want to replicate the model are also very valuable.

4. Participating Covered Entities

All participant(s) must be identified and eligible for the 340B program and must be listed in the OPA database. If a participant is not in the database, they are eligible and made application. The proposal should further document the commitment of the participating entities to take the necessary actions to implement the proposal. This should include current letters of support and/or contracts or agreements. Contracts do not have to be signed and in place to submit proposals but they should be ready for signature and implementation upon approval of the demonstration project. For Disproportionate Share Hospital applicants, it must be understood that the entire hospital cannot claim to be a participant if the covered entity is a distinct part of the hospital. Only clinics on the Medicare cost report will be considered as part of the covered entity.

5. Duration of Project

The maximum duration of time that a project may apply for is six years.

6. Inventory Control and Dispensing

Please provide a detailed description of how and when medications will be ordered and who will be (i.e. the entity, purchasing group, contract pharmacy, etc).

Does the proposal comply with all State pharmacy laws?

Certain states may require separate *physical* inventories (i.e. Florida)

Describe in detail the method for ordering and purchasing medications.

Description of the record system

Description of procedures taken for medications not picked up by eligible patients.

Describe how 3rd Party reimbursements will be handled.

How will the covered entity ensure that they will be filling prescriptions for eligible patients by eligible prescribers? How will eligible patients and prescribers be identified? How will this data be updated?

Clarify Medicaid billing procedures for all the participating entities. Will prescriptions to Medicaid patients be carved-out?

Describe the financial relationships between all parties. Include:

- How are 340B medications paid for, i.e., who is paying the bills?
- What will the reimbursements be?

Will separate physical inventories be used or a replenishment model? If using a replenishment model, what are the procedures?

Revised: 3/8/2010

7. Compliance with 340B statutory and Program Requirements

Does the proposal comply with all 340B statutory and program requirements?

8. Drug Diversion

Medicaid

- The Office of Pharmacy Affairs has the pharmacy Medicaid number, if Medicaid carve out is not being utilized.
- An appropriate system is in place to prohibit a request for a Medicaid rebate from the manufacturer on a drug purchased using 340B pricing.

Auditing

These demonstration projects require annual audits following standard business practices. These audits must be performed by an independent, outside auditor with experience auditing pharmacies.

The proposal should provide:

- Identification of the auditor and their experience in pharmacy auditing
- What will be audited?
- What audit trails will be provided to the auditor by the entity?
- What kind(s) of reports will be utilized to audit the pharmacy?

Drug diversion and duplicate discounts are a primary concern of OPA and all efforts to avoid these potential problems should be well explained.

Patient Eligibility

Does an in-house pharmacy serve the general (non-eligible) patients? If so, what are the procedures to ensure compliance with program requirements?

Please ensure and explain how the proposal meets the three criteria for the "[definition of a patient](#)":

1. Covered entity has a relationship with the individual that includes the maintenance of individual's health care record.
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that the responsibility for the care provided remains with the covered entity.
3. The individual receives a health care service or range of services from the covered entity which is consistent with the grant funding or Federally-qualified look-alike status (DSHs are exempt from this).

An individual ADAP client receiving financial assistance for payment of drugs under Title XXVI of the PHS Act will be considered a patient of the payor state ADAP.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Information Necessary for Networks of Covered Entities

- Is the applicant defined as a network for other purposes or by other organizations?
- Approval of overseeing State administrative bodies, if necessary.

Revised: 3/8/2010

- Identification of the lead entity, if one exists.
- Identification of which entity, if not all, will be driving income from sale of the medications, and consideration of how this reportable income will affect grants (if the covered entity is a grantee).
- Medication ordering, billing and distribution procedures.
- Medicaid billing procedures.

General Information to Consider

- Do the patients of the covered entity have the choice to receive medications (not at 340B discounts) and services from other pharmacies?
- Do all aspects of the proposal meet State Board of Pharmacy regulations?
- Include all contracts or agreements with parties involved. These do not have to be signed but do need to be ready for implementation upon proposal approval.
- Does the proposal violate the Anti-kickback statute?
- Please include a statement acknowledging that if the proposal is approved, it is subject to audit by manufacturers and the Healthcare Systems Bureau.