



STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES

Med-QUEST Division
Health Care Services Branch
P.O. Box 700190
Kapolei, Hawaii 96709-0190

March 14, 2013

MEMORANDUM

MEMO NO.

ACS M13-03

[Replaces ACS M12-04 dtd 5/24/12]

TO: 340B Covered Entities

FROM:  Kenneth S. Fink, MD, MGA, MPH
Med-QUEST Division Administrator

SUBJECT: REPORTING REQUIREMENT OF NON-340B MEDICATIONS TO COMPLY
WITH THE AFFORDABLE CARE ACT (ACA) MEDICAID MEDICATION
REBATE PROGRAM

The Department of Human Services, Med-QUEST Division (MQD) is issuing this memorandum in response to changes under the Affordable Care Act to the Medicaid medication rebate program. The purpose is to communicate a new process that facilitates exclusion of 340B medications from utilization data for rebate calculations by requiring reporting of NON-340B medications dispensed by 340B covered entities. This memo replaces ACS M12-04 that was dated May 24, 2012.

The Omnibus Budget Reconciliation Act of 1990 requires that medication manufacturers enter into rebate agreements with Centers for Medicare & Medicaid Services (CMS) for outpatient dispensed and administered medications provided to Medicaid eligible beneficiaries in the fee-for-service (FFS) Medicaid Program. Federal Financial Participation (FFP) is extended only for those outpatient medications covered under a manufacturer's rebate agreement with CMS.

Section 2501 of the ACA of 2010 expanded the collection of rebates to include outpatient medications covered by Medicaid managed care organizations (MCOs). As of March 23, 2010, all MCOs are required to report utilization to the State Medicaid agency so that manufacturers can be billed for medication rebates. (However, CMS allows MCOs to continue to provide outpatient medications from manufacturers that do not have rebate agreements with CMS.)

The Health Resources and Services Administration (HRSA) identifies 340B covered entities as providers that purchase 340B medications at discounted rates. The covered entity types most common in Hawaii include clinics (such as Federally Qualified Health Centers and family planning clinics such as Planned Parenthood), disproportionate share hospitals, children's hospitals, critical access hospitals, and sole community hospitals. Covered entities have the option of using 340B medications for Medicaid eligibles and non-Medicaid eligibles. Covered entities may dispense/administer 340B and non-340B medications.

CMS and MQD will use utilization data from the FFS program and MCOs for the purpose of rebate collection. Medications purchased under the 340B program are already discounted and are not eligible for this rebate. MQD must exclude 340B utilization data from the utilization data and rebate calculations. However, development of a methodology to exclude the 340B medications from the medication utilization data has identified significant challenges including the following:

- 340B medications do not have special identifiers. The typical identifier, the NDC number, is the same for 340B and non-340B medications (i.e., medications acquired from wholesalers/distributors).
- Covered entities are not required to maintain a 340B inventory and a separate non-340B inventory. They are allowed to have a "virtual" inventory. Thus, at any point in time, a covered entity can dispense/administer a medication using non-340B inventory and then purchase a 340B medication to replace the non-340B medication used.

After much discussion with 340B covered entities and recognition that the vast majority of their medications dispensed to Medicaid beneficiaries receiving services through managed care are purchased through the 340B program, the MQD has developed an approach to obtain medication utilization data that excludes 340B medications. Instead of requiring use of a separate NPI, modifier, or other coding changes, MQD will require reporting of NON-340B medications reimbursed by a health plan contracted with MQD. The main advantages of this approach include the following:

- 340B medications from all covered entities that use them for Medicaid eligibles will be handled the same, regardless of how the covered entities bill medications.
- Covered entities will not need to identify that a medication is a 340B medication at the time it is administered or dispensed.
- Covered entities can continue to bill 340B medications as instructed by the FFS program and contracted health plans.

The following is the approach for identifying NON-340B medications for the purpose of claiming drug rebates:

- This memorandum is being sent to you because you have been identified as a 340B covered entity that dispenses medications to Medicaid beneficiaries enrolled in a MQD contracted health plan. Please confirm this information by completing the attached form (Attachment A) and submitting it to MQD no later than April 5, 2013.
- On a quarterly basis, all 340B covered entities will submit to the MQD a report in Excel 2010 or lower format that identifies all NON-340B medications that were dispensed to Medicaid beneficiaries and paid by a MQD contracted health plan (e.g., QUEST or QExA health plan) in the prior quarter. Please see Attachment B for report format and instructions.
- The first reporting period will be the second quarter of 2013 (April 1, 2013 to June 30, 2013).
- Reports shall be submitted by the twenty-first (21st) day of the month (or next business day) following the end of the quarter (i.e., quarter ending June 30, 2013, report submitted no later than July 22, 2013).
- The medication must have a claim payment date by the last day of the quarter. For example, if the quarter ends June 30, 2013, medications paid before April 1, 2013 or after June 30, 2013 should not be included. However, if a medication was paid before the start of the quarter, but not previously reported, this medication should be submitted. For example, if a medication was dispensed on December 15, 2013, but not included in the quarter ending December 31, 2013 report, it should be included in the quarter ending March 31, 2014 report.
- All 340B covered entities that dispense medications to Medicaid beneficiaries enrolled in a MQD contracted health plan must submit a report quarterly. If the 340B covered entity was not paid for any NON-340B medications during the quarter, then a report should be submitted timely with the **1. Reporting Quarter;** and **2. NPI number** completed.

NOTE: Reports should NOT be submitted for NON-340B medications dispensed/administered to Medicaid beneficiaries in the fee-for-service (FFS) program at the time of service.

- Reports should be submitted to MQD through the following process:
- Reports in Excel 2010 or lower format are submitted through the Secure File Transfer Server (SFTS) at https://sftp.statemedicaid.us/Pharmacy_Qtrly_Reports/340B_Medication_Processing/. A folder named after your 340B entity name will be displayed. Within this folder, please upload the reports to the "OTHER" folder.

- Anyone responsible for submitting these reports will need to enroll for an Individual User Account on the SFTS. Current SFTS users will need to complete a new enrollment form to obtain access to their assigned 340B folder.
- Please contact the EDI Helpdesk at hi.ecstest@xerox.com to obtain a DHS 1188A Med-QUEST Electronic Data Interchange Request form to gain access to your 340B folder.
- Detailed instructions on submission of 340B reports will be provided for each successful SFTS enrollment.
- Although spreadsheets must be submitted on a quarterly basis, please note that your Individual User Account password on the SFTS will expire every sixty (60) days. To avoid having your password expire, we advise that you change your SFTS password prior to expiration.

The MQD needs to be compliant with the requirements of Section 2501 of the ACA. The approach described in this memo allows the State to receive the full rebate to which it is entitled and not claim unallowable rebate. We appreciate your assistance in complying with these reporting requirements.

If you have any questions or concerns regarding the content of this memo, please call Gary Peton at 952-5591 or Patti Bazin via e-mail at pbazin@medicaid.dhs.state.hi.us or telephone at 692-8083.

Enclosures

c: QUEST and QExA health plans

INSTRUCTIONS QUARTERLY REPORT FOR 340B COVERED ENTITIES

PURPOSE

340B Covered Entities shall report non-340B medications paid by QUEST/QExA health plans quarterly for the purpose of collection of data to support payment of drug rebates by drug manufacturers.

- Reports shall be submitted by the twenty-first day of the month or next business day following the end of the quarter (i.e., quarter ending 03/31/13, report submitted no later than 04/22/13).
- The medication must have a service or payment date by the last day of the quarter. For example, if the quarter ends 03/31/13, no service or paid dates 04/01/13 or beyond shall be submitted. However, if a medication was paid before the start of the quarter, but not previously reported, this medication should be submitted. For example, if a medication was dispensed on 12/15/12, but not included in the quarter ending 12/31/12 report, it should be included in the quarter ending 03/31/13 report.
- All 340B entities must submit a report quarterly. If the 340B entity did not dispense any non-340B medications over the quarter, then a report should be submitted timely with the **1. Reporting Quarter** and **2. NPI number** completed.

INSTRUCTIONS FOR COMPLETING THE SPREADSHEET

1. Reporting Quarter

Enter the calendar year quarter and calendar year as follows:

- 1 Q 20XX January 1 to March 31
- 2 Q 20XX April 1 to June 30
- 3 Q 20XX July 1 to September 30
- 4 Q 20XX October 1 to December 31

Report only one (1) quarter per spreadsheet

2. Provider_ID

Enter your covered entity's 10 digit NPI number. Must correspond to NPI number provided to the Med-QUEST Division on the "340B Provider Information: form.

3. Labeler_Code

Enter the first 5 digits of the NDC number

4. Product_Code

Enter the next 4 digits of the NDC number

5. Package_Size

Enter the last 2 digits of the NDC number

6. Last_Name

Enter the recipient's last name

7. Record_number

The paid claim number provided by the QUEST/QExA health plan. (The claim number on the remittance advise from the QUEST/QExA health plan)

8. Payer Plan Name

Enter the first letter of the name of the health plan that paid and assigned the record number in 7. Enter one of the following:

- A = AlohaCare
- H = HMSA
- K = Kaiser
- U = United
- O = Ohana

9. Service_Date

Enter the date the drug was dispensed or administered in the format CCYY-MM-DD

10. Paid_Date

Enter the date that the QUEST/QExA plan paid the drug in the format CCYY-MM-DD

11. Number_of_Units

Enter the NCPDP units (each, ml, gm, etc.) dispensed or administered

12. Reimbursement_amount

Enter the amount paid by the recipient's QUEST/QExA health plan

13. Adjustment_Code

Enter O—original; Q—reversal, R—replacement, or V—void

To report changes to an original claim, use the original record number report in 7 as follows:

- If the claim is being reversed and replaced with another paid amount. Report the original (previously paid) claim number with a Q (reversal) adjustment code on one line and report a new claim number with the R (replacement code) on the following line.
- If the claim is being reversed without replace, report the original claim number and use the V (void) adjustment code

14. Patient_ID (HAWI)

Enter the 10 digit Medicaid recipient ID number. Example: 0000012345

340B Provider Information

Provider Name	A Medicaid Provider ID Number	A NPI Number	A 340B ID Alpha Numeric

Check the block that best describes the provider identified above:

- Provider is a 340B covered entity that **ONLY** dispenses/administers 340B drugs for its clients in QUEST/QExA. (Provider does not dispense/administer non-340B drugs and does not submit claims to QUEST/QExA for non- 340B drugs.) **This group does not need to submit a report to Med-QUEST Division quarterly.**
- Provider is a 340B covered entity that dispenses/administers non-340B drugs and 340B drugs to its clients in QUEST/QExA and submits claims to QUEST/QExA for both 340B drugs and non-340B drugs. **If this block is checked, the provider is required to submit quarterly reports on non-340B drugs paid by QUEST/QExA.**
- Provider is a 340B covered entity that **ONLY** dispenses/administers non-340B drugs to its clients in QUEST/QExA and only submits claims to QUEST/QExA for non-340B drugs. **This group does not need to submit a report to Med-QUEST Division quarterly.**
- None of the blocks above describe the provider.

Explain _____

Print Contact Name	Signature	Title
Phone Number	Date	

Please complete information above by April 4, 2013 and return this form to:

Med-QUEST Division
 HCSB
 P.O. Box 700190
 Kapolei, Hi 96709-0190

