



STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES

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

September 11, 2017

MEMORANDUM


MEMO NO.

QI-1715

CCS-1703

[Supersedes ACS M13-03]

TO: 340B Covered Entities, QUEST Integration (QI) and Community Care Services (CCS) Health Plans

FROM:  Judy Mohr Peterson, PhD
Med-QUEST Division Administrator

SUBJECT: REPORTING REQUIREMENTS FOR 340B MEDICATIONS PROVIDED BY CONTRACT PHARMACIES AND **NON**-340B MEDICATIONS PROVIDED BY 340B COVERED ENTITIES TO QUEST INTEGRATION (QI) AND COMMUNITY CARE SERVICES (CCS) MEMBERS

A series of memoranda will be issued to address the Office of the Inspector General's Hawaii audit on medication rebates. This memorandum replaces ACS Memo M13-03 dated March 14, 2013.

The Med-QUEST Division's (MQD's) purpose in issuing this memorandum is to ensure that 340B medications are excluded from Medicaid rebate calculations by:

- Providing a mechanism for pharmacies contracted by covered entities to dispense 340B medications (contract pharmacies) to exclude the 340B medications they provide to QI/CCS members from Medicaid rebate calculations.
- Clarifying MQD's requirements for new and existing covered entities to notify the MQD of their use of Non-340B medications provided to QI/CCS members.

A. GENERAL:

The Omnibus Budget Reconciliation Act of 1990 required that medication manufacturers enter into rebate agreements with the Centers for Medicare and 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) extended only for those outpatient medications covered under a manufacturer's rebate agreement with CMS.

Section 2501 of the Affordable Care Act (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 and non-Medicaid eligibles. Covered entities may dispense/administer 340B and Non-340B medications. HRSA also required contract pharmacies (pharmacies contracted by covered entities to dispense 340B medications) to report utilization/dispensing of 340B medications.

42 USC 256b(a)(5)(A)(i) prohibits duplicate discounts. Thus, manufacturers that provide 340B medication at discounted rates to covered entities should not be also providing Medicaid rebates for the same medication. Therefore, ALL 340B medications must be excluded from the medication utilization data sent by MCOs to MQD for rebate collection.

MQD developed a process for covered entities to identify Non-340B medications for inclusion in Medicaid rebate collection. This process will be reiterated in Section C of this memorandum. However, MQD did not address how pharmacies contracted by covered entities to provide 340B medications to QUEST Integration (QI) or CCS members should identify 340B medications. Section B of this memorandum addresses this issue.

B. 340B CONTRACT PHARMACIES

- MQD realizes that contract pharmacies provide outpatient medications to non-QI or non-CCS members, QI/CCS members who are not patients of covered entities, and to patients of the covered entities with which they have contracts to provide 340B medications. MQD understands that most of the outpatient medications dispensed by retail pharmacies are NOT 340B medications.
- To expedite the identification of 340B medications provided by contract pharmacies on behalf of the covered entities with which they have contracts, MQD has decided that all contract pharmacies **MUST** identify all 340B medications billed to the QI or CCS plans in which the members are enrolled. **This change shall be effective for all medications dispensed beginning October 1, 2017.**
- This shall be indicated in the Claim Billing (B1) transaction in the field Submission Clarification Code (420-DK) with the value of 20. The description of Value code 20 is as follows:

Field	Value	Description
Submission Clarification Code (420-DK)	20	340B - Indicates that, prior to providing service, the pharmacy has determined the product being billed is purchased pursuant to rights available under Section 340B of the Public Health Act of 1992 including sub-ceiling purchases authorized by Section 340B (a)(10) and those made through the Prime Vendor Program (Section 340B(a)(8)).

- For details on this process please consult the 340B Information Exchange Reference Guide developed by the NCPDP (National Council for Prescription Drug Programs). The link to this guide is:
[https://www.ncpdp.org/NCPDP/media/pdf/340B Information Exchange Reference-Guide v1-0.pdf](https://www.ncpdp.org/NCPDP/media/pdf/340B%20Information%20Exchange%20Reference-Guide%20v1-0.pdf)

C. 340B COVERED ENTITIES

- 340B medications for all covered entities that use them for Medicaid beneficiaries 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 fee-for-service (FFS) Medicaid program and its QI/CCS plans.
- Covered entities that have not submitted or have made changes to their use of 340B medications should submit the attached form (Attachment A) to MQD within six months.
- The attached form (Attachment A) must also be completed and mailed to the MQD when the covered entity has changed its medication policy and provides both 340B and Non-340B medications to QI/CCS members.
- On a quarterly basis, all 340B covered entities that provide Non-340B medications 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. QI health plan) in the prior quarter. Please see Attachment B for report format and Attachment C for instructions.
- 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 December 31, 2017, report submitted no later than January 22, 2018).

The medication must have a claim payment date by the last day of the quarter. For example, if the quarter ends December 31, 2017, medications paid before October 1, 2017 or after December 31, 2017 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 October 15, 2017, but not included in the quarter ending December 31, 2017 report, it should be included in the quarter ending March 31, 2018 report.

- NOTE: Reports should NOT be submitted for Non-340B medications dispensed/administered to Medicaid beneficiaries in the 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 [http://sftp.statemedicaidus/Pharmacy Qtrly Reports/340B Medication Processing/](http://sftp.statemedicaidus/Pharmacy%20Qtrly%20Reports/340B%20Medication%20Processing/). 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@conduent.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 in 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.

D. HEALTH PLANS

All Medicaid prescription drug claims shall require National Drug Code (NDC) information. The requirement includes all drugs billed by Healthcare Common Procedure Coding System (HCPCS) codes, including all J codes and other alpha-numeric drug codes submitted by their contracted providers. Health plans are required to provide NDC information for all HCPCS drug code reimbursements. The MQD SHALL NOT accept HCPCS drug code claims without NDC information.

MQD required Medicaid contracted health plans to submit a monthly drug rebate file and identify all 340B medications. The health plans shall utilize the updated format (Attachment D) for all submissions to MQD. Effective October 1, 2017, all Medicaid contracted health plans are required to include the field 393 (340B claim indicator) in the rebate file. The field indicator should be Y (YES) when the health plan's contracted providers report a medication to be a 340B medication. The field should be N (No) when the medication is not a 340B medication.

The following naming convention shall be used for each monthly file submission:
PDR_XXYYMM.txt

Zipped files and trailer files are no longer required. The plan specific file names are:

PDR_ALYYMM.txt = AlohaCare

PDR_HMYYYMM.txt = HMSA

PDR_KPYYMM.txt = Kaiser

PDR_OMYYMM.txt = Ohana Medical

PDR_OPYYMM.txt = Ohana Pharmacy

PDR_UHYYYMM.txt = United Healthcare

The health plans shall ensure that all the participating pharmacies are notified of the requirements described in this memo. Failure to provide required information will result with financial sanctions.

If you have any questions or concerns regarding the content of this memo, please call Gary Peton, Conduent Pharmacy manager, at 952-5591 or Jon Fujii via e-mail at jfujii@dhs.hawaii.gov.

Attachments

c: 340B Covered Entities, QI and CCS health plans