

**STATE OF HAWAII**  
**DEPARTMENT OF HUMAN SERVICES**

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

September 9, 2022


MEMORANDUM

MEMO NO.

QI-2213 [Replaces QI-1715]

CCS-2206 [Replaces CCS-1703]

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

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

SUBJECT: CLARIFICATION OF REPORTING REQUIREMENTS FOR MEDICATIONS PROVIDED BY 340B  
CONTRACT PHARMACIES TO QUEST INTEGRATION (QI) AND COMMUNITY CARE SERVICES  
(CCS) MEMBERS

The purpose of this memorandum is to provide an update to 340B covered entities on the reporting of 340B medications dispensed by their contracted pharmacies to QI and CCS health plan members. This memo replaces QI-1715 and CCS-1703 which was previously issued on September 11, 2017.

The federal regulations described in Attachment A require all 340B covered entities to identify 340B medications to ensure that these medications are excluded from Medicaid rebate collection. It is the responsibility of 340B covered entities to accurately report 340B medications to QI and CCS health plans.

MQD contacted 340B covered entities to understand how they are inventorying and reporting 340B medications and has learned that 340B medications are not being consistently excluded for Medicaid rebate collection.

MQD learned from a survey conducted in 2021 that most 340B covered entities use 340B TPAs (Third Party Administrators) to manage 340B medications dispensed by contract pharmacies. The TPAs intended for their contract pharmacies to properly report 340B medications through the point-of-sale system, using value code 20. However, after claim reviews conducted in 2022, it became clear to MQD that the value code 20 is not being reported by contract pharmacies. See Attachment A for a description of the value code 20. Thus, MQD will be contacting 340B covered entities and their 340B TPAs to remind them of the importance of identifying and reporting 340B medications to QI and CCS health plans. In addition to the current value code 20 reporting option, MQD will also provide a flat file option (see Attachment A) to report 340B medications to QI and CCS health plans.

If the flat file option is selected, the 340B covered entity will report the 340B medications to each QI and CCS health plan. Then each health plan will exclude these medications from its rebate report.

Implementation Timeline:

<b>Milestones</b>	<b>Due Date</b>
MQD will send letter to 340B covered entities	Week of September 12, 2022
340B covered entity to return completed form to MQD	September 30, 2022
Health plan to setup secured delivery site for flat file submissions	October 28, 2022
Due date for first 340B medications flat file report to the QI and CCS health plans	January 15, 2022

After the implementation of the first 340B medications flat file report, covered entities or their TPAs shall submit the 340B medications flat file report quarterly, by the 15<sup>th</sup> of the month following the end of each quarter. Reports are due on January 15, April 15, July 15, and October 15 of each year. See Attachment A for further details of the 340B medications flat file report and submission.

It is important to MQD that we have up-to-date information on your 340B covered entity's management of 340B medication. If your 340B covered entity has made or is planning to make any changes to its policy of providing 340B medication to QI and CCS health plan members, please report any of the changes below to KelliAnn Komatsu at [kkomatsu@dhs.hawaii.gov](mailto:kkomatsu@dhs.hawaii.gov) within one month of the change.

- Your 340B covered entity no longer provides 340B medications to members of QI and CCS health plans
- Your 340B covered entity has decided to provide 340B medications to members of QI and CCS health plans and will manage and report 340B medications to QI and CCS health plans
- Your 340B covered entity has decided to provide 340B medications to members of QI and CCS health plans and will manage and report 340B medications to QI and CCS health plans and also use one or more 340B TPAs to manage and report 340B medications to members of QI and CCS health plans
- Your 340B covered entity has decided to provide 340B medications to members of QI and CCS health plans and to use one or more 340B TPAs to manage and report 340B medications to QI and CCS health plans
- Your 340B covered entity no longer uses a 340B TPA and will manage and report 340B medications to QI and CCS health plans

The QI and CCS health plans shall ensure that all the participating pharmacies are notified of the requirements described in this memo. QI and CCS health plans shall review and submit clean reports to MQD. Failure to provide required information will result with contract remedy actions.

If you have any questions or concerns regarding the content of this memo, please call Gary Peton, Conduent Pharmacy manager, at (808) 952-5591.

Attachment

ATTACHMENT A  
340B Federal Regulations and Reporting Requirements

**A. Federal Regulations:**

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.

**B. 340B Reporting Requirements**

1. Report Submission Option

340B covered entities may report 340B medications by either submitting claims with value code 20 and/or submitting a flat file. Reports shall be submitted to each contracted health plan.

a. Value 20

This shall be indicated in the POS 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)).

b. Non-POS Billing

On electronic and hard copy UB04 hospital outpatient claims and CMS 1500 claims—either the modifier TB or JG can be attached to the HCPCS drug code followed by N4 with the NDC#. The description of TB is “Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.” The description of JG is “Drug or biological acquired with 340B drug pricing discount.”

c. Flat File Format (Excel)

Table below identifies the format and requirements to submit an excel flat file to each contracted health plan.

340B Claim - Flat File Format					
Contents	Field Position Delineated			Mandatory/Optional	Notes
	Length	Start	End	Pharm	
first_char	1	1	1	M	POS claims set to \$
claim_id	20	2	21	M	Claim unique numerical identifier
provider_id	20	22	41	M	NPI
labeler_code	5	42	46	M	Include leading zeroes
product_code	4	47	50	M	Include leading zeroes
package_size	2	51	52	M	Include leading zeroes
left blank	16	53	68		
first_name	30	69	98	O	
last_name	30	99	128	M	
mid_init	1	129	129	O	
left blank	3	130	132		
left blank	1	133	133		
rx_num	20	134	153	M	Prescription Number
service_dt	10	154	163	M	CCYY-MM-DD

paid_dt	10	164	173	M	CCYY-MM-DD. Should be actual date paid if available.
left blank	1	174	174		
left blank	1	175	175		
left blank	3	176	178		
num_of_units	14	179	192	M	Report as negative to reverse a claim previously reported non-340B
left blank	13	193	205		
left blank	12	206	217		
left blank	13	218	230		
left blank	13	231	243		
reimbursement_amt	13	244	256	M	Report as negative to reverse a claim previously reported non-340B
adjustment_cd	1	257	257	M	V- Void for a claim previously reported non-340B
prev_claim_id	20	258	277	M	Plan's original PDR claim ID (Plan will need to supply)
left blank	2	278	279		
left blank	4	280	283		
left blank	1	284	284		
left blank	8	285	292		
client_id	10	293	302	M	HAWAII
group_id	10	303	312	M	3000
plan_id	10	313	322	M	290
left blank	15	323	337		
left blank	15	338	352		
patient_id	20	353	372	M	HI Medicaid ID
left blank	4	373	376		
left blank	1	377	377		
left blank	13	378	390		
left blank	2	391	392		
340B claim ind	1	393	393	M	Use N
line_number	4	394	397	M	Usually 0001, but compound drugs will have multiple lines.
Numerics in current files are left-justified with decimal points present, no zero padding.					
Visible decimal points are nice though.					

2. Flat File Report Due Dates

340B covered entities submitting a 340B medication flat file report shall submit it to each contracted health plan by the fifteenth (15th) day of the month (or next business day) following the end of the quarter (i.e., quarter ending December 31, 2022, report submitted no later than January 16, 2023).

The medication must have a claim payment date by the last day of the quarter. For example, if the quarter is from October to December 2022, medications paid before October 1, 2022 or after December 31, 2022 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, 2022, but not included in the October to December 2022 report, it should be included in the next quarter's report (January to March 2023).

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