

DHCS 340B Drug Pricing Self-Audit Requests

Insights

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We want to alert you to a new, expansive “self-audit” audit request by the California Department of Health Care Services Audits and Investigations Branch (the “Department”) regarding billing to the Medi-Cal program for drugs acquired under the 340B Drug Pricing Program.

In recent weeks, the Department has sent letters to 340B covered entities and contract pharmacies entitled “Demand for Self-Audit of 340B Program Overpayments.” The letters appear to be form letters, often not tailored to the recipient. The Department apparently is concerned about the application of Welfare and Institutions Code section 14105.46, which states, in relevant part, “A covered entity shall dispense only 340B drugs to Medi-Cal beneficiaries.” The sentence is short, but the application and relationship between covered entities, contracted pharmacies, and third-party administrators is complicated.

The Department’s form letter emphasizes that Section 14105.46 limits charges billed to Medi-Cal for 340B drugs to the provider’s “actual acquisition costs.” The Department indicates that recipients may have been overpaid by billing in excess of their actual acquisition costs for 340B drugs, and directs recipients to conduct a self-audit for the period December 1, 2016 through December 31, 2019.

Responding to any government inquiry, including self-audit requests, is serious. The Department documents its position in the audit request letter that the self-audit is warranted for contract pharmacies and covered entities to consider whether they may have received overpayments that could trigger report and repay obligations. However, the Department does not appear to consider the fact that arrangements between contract pharmacies and covered entities (and their third party administrators) can vary significantly, and whether and how each party bills drugs under the 340B program is a critical element in crafting an appropriate response to the Department.

We are working with several clients to respond to the Department’s self-audit demand letters. We have also been in contact with several trade associations whose members have reached out to them concerning the audit demands. There are important legal considerations when responding. The Department may not fully understand arrangements between covered entities and contract pharmacies concerning 340B drugs, and responses may require careful explanations of these arrangements.

If you would like more information about this issue, please contact [Joseph LaMagna](#) at (619) 744-7305, [Nina Marsden](#) at (310) 551-8153, or [Lloyd Bookman](#) at (310) 551-8185.

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