

# Exhibit M



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January 6, 2021

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**Via Email**

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Re: **HHS Advisory Opinion 20-06**

Dear Mr. Asay and Ms. Dixon:

On behalf of University of Washington Medical Center (“UWMC”) and Harborview Medical Center (“HMC”) (collectively, “UW Medicine Hospitals”), we write with regard to your continued policies unlawfully restricting covered entities’ ability to purchase covered outpatient drugs at 340B prices through contract pharmacies. UW Medicine Hospitals have previously reached out with regard to the unlawfulness of your policy, under both statutory and regulatory provisions, and the negative impact your policy is having on UW Medicine Hospitals and their patients, especially during the fight against COVID-19.

Since the time of our original correspondence, the Department of Health and Human Services (“HHS”) has issued Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program.<sup>1</sup> This Advisory Opinion makes clear, as UW Medicine Hospitals’ previous correspondence has explained, that “to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.” Further, the Advisory Opinion outlines that the statutory language, the Pharmaceutical Pricing Agreement (“PPA”), and the purpose and the history of the 340B Program all support this conclusion. In light of the Advisory Opinion your continued denial

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<sup>1</sup> Available at [https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020\\_0.pdf](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf).

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of 340B pricing puts Lilly's PPA and reimbursement under the Medicaid and Medicare Part B programs at risk, and subjects Lilly to civil monetary penalties for each overcharge or denied purchase.

Given the Advisory Opinion and the numerous other indications from both government and industry authorities that your policy with regard to contract pharmacies is unlawful and harmful to covered entities, we ask that you revoke your policy effective immediately. We also ask that you reverse any transactions where you have charged UW Medicine Hospitals above the applicable ceiling price for 340B covered outpatient drugs, and compensate UW Medicine Hospitals for its losses otherwise incurred in being blocked from purchasing covered outpatient drugs at 340B pricing through its contract pharmacies.

It is UW Medicine Hospitals' intent to seek reimbursement of these losses through administrative action, including applicable fees and costs, should you not reverse your policy. Given the negative impacts of your policy and the need to seek administrative relief, we would appreciate your swift response by January 14, 2021.

Sincerely,

A handwritten signature in black ink that reads "Jessica Andrade". The signature is fluid and cursive.

Jessica M. Andrade

JMA:jma