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June 13, 2025

SENT VIA ELECTRONIC MAIL

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Re: MED-Project USA Comments on the Drug Takeback Solutions Foundation Updated Proposal

Dear Mr. Lee,

MED-Project USA ("MED-Project") appreciates the opportunity to comment on the Drug Takeback Solutions Foundation ("Foundation") updated proposal ("Updated Proposal") and Variance Requests dated May 19, 2025.

MED-Project develops, implements, and operates stewardship programs for Covered Drugs on behalf of hundreds of participating Covered Manufacturers. MED-Project has substantial, practical, on-the-ground experience implementing unwanted medicine takeback programs in jurisdictions across the country, including the State of Oregon. MED-Project has served the residents of the State since 2021. MED-Project continues to administer an approved Product Stewardship Plan for Covered Drugs from Households ("Plan") in the State of Oregon.

MED-Project has collected over 238,000 pounds of Covered Drugs in the State through a wide network of service locations that includes reasonably and conveniently located Drop-Off Sites and Mail-Back Distribution Locations. MED-Project's comprehensive outreach and education program has generated close to 38 million impressions to State residents. MED-Project has provided the Oregon Department of Environmental Quality ("Department") with timely and transparent annual and monthly reporting providing detailed updates on MED-Project's implementation progress of the currently approved Plan. MED-Project has consistently met Plan goals and the implementation timeline during the four years of operation.

As described below, MED-Project submits these comments on the Foundation's Updated Proposal with concerns with the content of the Updated Proposal and the Variance Requests. MED-Project looks forward to what the Department approves as it will further inform what requirements have been established through the approved plans. MED-Project expects any approved plan and related information, including any

rejections or approvals will be made public so that Program Operators have equal access to information and can benchmark appropriately.

MED-Project appreciates the Department's consideration of its comments and looks forward to continued engagement with the Department throughout this process.

The Foundation's Updated Proposal Does Not Demonstrate Adherence to Oregon Drug Take-Back Law and MED-Project's Understanding of the Department Guide for Oregon Drug Take-Back Programs.

Aspects of the Foundation's Updated Proposal do not appear to meet the requirements set forth in Oregon Drug Take-Back Law and do not conform to the Guide for Oregon Drug Take-Back Programs ("Guide") as MED-Project understands it. On March 27, 2025, the Department published the Guide. MED-Project understands that the Guide was to be used by Program Operators in submitting updated plan proposals. MED-Project drafted its updated plan proposal to be in alignment with the legislation and the Guide. It appears that the Foundation's Updated Proposal fails in numerous examples to conform to the Guide as MED-Project understands is outlined.

MED-Project should be allowed to resubmit the MED-Project Product Stewardship Plan for Covered Drugs from Households submitted on May 19, 2025 to align with the Department's understanding of compliance with the legislation and the Guide if the Department approves the Foundation's Updated Proposal as written.

The Foundation's Updated Proposal Cannot Commit MED-Project To Provide Program Services.

The Updated Proposal appears to commit MED-Project to coordinate and message alignment, Updated Proposal at 22. MED-Project is not aware of any legislation or regulations that allow one Program Operator to commit another Program Operator to any required action. As another example, the Updated Proposal commits to a unified color palette across all materials, Updated Proposal at 22. Additionally, the Updated Proposal states "All Program Operators deploy a uniform, co-branded logo on websites, kiosks, outreach materials, and advertising to ensure programmatic consistency and public recognition across Oregon." Updated Proposal at 26. MED-Project coordinated with the Foundation in developing the common mark but the Updated Proposal goes beyond by indicating MED-Project will use the common mark as the Foundation sets forth in the Updated Proposal.

The Foundation's Updated Proposal is Unclear if Costs of Insurance is Covered Under the Insurance Program of Its Service Provider.

Based on what is unredacted regarding "Insurance," the Updated Proposal indicates that the Foundation's insurance program would be covered by its Service Provider. *But see* Updated Proposal at 25 ("The Foundation shall retain sufficient staff and maintain insurance coverage adequate to support Program operations throughout the six-month wind-down period"). The Updated Proposal lists Inmar Rx Solution, Inc. ("Inmar") as the Service Provider. Oregon Revised Statute 459A.233 requires that all costs of a drug take-back program must be paid by the covered manufacturers. MED-Project understands that all costs of a drug take-back program to include associated insurance expenses. In this context, if the Foundation is insured by its Service Provider, are those costs being absorbed by Inmar rather than charged to the participating covered manufacturers? Such an arrangement would appear to be prohibited by statute.

<u>The Foundation Variance Requests Do Not Appear to Satisfy its Obligations</u> under the Oregon Drug Take-Back Law.

The Foundation's two Variance Requests do not appear to meet the Foundation's obligations for services in place of required Drop-Off Sites.

For example, the Updated Proposal indicates that the Foundation has not established Drop-Off Sites in 152 Population Centers. The Foundation submitted what seems to be two Variance Requests. One identified four Population Centers (Dunes City, Johnson City, King City and Maywood Park) that the Foundation requested a four-year variance (that presumably applies prospectively) for being in close proximity to existing Drop-Off Sites. The other being a waiver from the Drop-Off Site requirement for five counties (Curry, Grant, Morrow, Sherman, Wheeler) which have a total of 24 Population Centers for providing mail-back services. Without taking the merit of these Variance Requests into account, it seems that the Foundation is lacking a Variance Request for 124 Population Centers.

Additionally, per ORS 459A.218(3), a drug take-back program that is unable to establish and maintain a sufficient number of Drop-Off Sites to meet the requirements of its plan shall provide alternate services, such as mail-back services, and hold collection events to ensure the convenient service described in the plan, subject to approval by DEQ. Oregon Administrative Rule 340-098-0350 sets forth factors that DEQ will consider in reviewing requests to provide services and hold collection events per ORS 459A.218(3). If DEQ accepts the comprehensiveness and level of detail provided in the Foundation's Variance Requests, it must apply those same standards to MED-Project.

Thank you for considering MED-Project's comments on the Updated Proposal.

Sincerely yours,

Dr. Victoria Travis, PharmD, MS, MBA

National Program Director

MED-Project USA