

84 FR 63108:

*Comment:* One commenter requested that CMS consider the potential additional burden on reporting entities based on the expanded definition of covered recipients.

*Response:* We recognize that there is an increased data reporting requirement associated with implementation of these statutory requirements, but the expanded definition is required by statute. The estimated burden of Open Payments program is outlined under OMB control number 0938–1237. Section VII.F.7.a. of this final rule provides an estimate of the anticipated regulatory impact, although section 6111(c) of the SUPPORT Act states that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient. As implementation plans are made, we will work to provide guidance, technical assistance, and operational efficiencies to help reduce the potential burden as much as possible.

*Comment:* One commenter further stated that they believe the burden estimate to add DI information to the Open Payment dataset is greater than CMS assumed. The commenter would like to provide input to CMS on the implementation of this requirement.

*Response:* When making this burden estimate, we took into account all of the current reporting entities and the array of demographics. We divided the group into several smaller categories based on entity size and made assumptions about the effort needed to make system and process changes. We assume that our estimates for each category will be low for some entities, but high for others. As we work through implementing these changes, we hope stakeholders will continue to provide feedback during working sessions to ensure our data collection system is easy to use and provides clear information.