Comment Number	Common Theme	Summary of Comment	Response
1	Timing of Collection	It is unrealistic that collection can begin by July 1, 2021. The collection should be delayed a year for parties affected by the proposed collection to make the necessary adjustments to IT systems and amendments to contracts with issuers, as well as focusing on COVID-19.	In response to public comments and the COVID-19 public health emergency, we are delaying collection until at least January 1, 2022.
2	Collect from PBMs Authorization	Commenters asserted the statute does not authorize collection directly from Pharmacy Benefit Managers (PBMs) or that it conflicts with 45 CFR 156.295, which requires Qualified Health Plan (QHP) issuers to submit the data.	For clarity, we intend to make regulatory revisions to require PBMs that contract with QHP issuers to manage prescription drug coverage to report the data prescribed by § 1150A(a)(2). With such a revision, a QHP issuer would be required to report the data prescribed by § 1150A(a)(2) only when the QHP issuer does not contract with a PBM to manage prescription drug coverage. Regardless, the statute permits collection directly from PBMs.
3	Bona Fide Service Fees	The statute does not authorize the collection of data for *bona fide* service fees.	We are removing the data element "*Bona Fide* Service Fees" from the collection template in the 30-day Paperwork Reduction Act (PRA) package.
4	NDC Level Authorization	The statute does not authorize collection at the National Drug Code (NDC) level, as it requires collection of data at "aggregate amount[s]."	While the statute does require reporting at the "aggregate amount," it does not further define this term. The collection's interpretation of "aggregate amount" to mean the "aggregate amount" of NDC is consistent with the Medicare Direct and Indirect Remuneration (DIR) reporting requirement. We seek to align this collection with the Medicare collection to the greatest extent possible. It is also a reasonable interpretation, as collecting drugs at a less detailed level would not the provide useful information Congress intended for collection.
5	Reliance on DIR Authority	The collection conflates authorization that applies only to the DIR reporting requirement which requires Part D sponsors to provide to HHS the information it determines to be necessary for carrying out the payment provisions of Part D, including calculating reinsurance and risk corridor payments to Part D plans.	We recognize that the DIR reporting requirement may utilize additional authorities besides section 1150A. A collection from QHP issuers and their PBMs at the NDC level is properly authorized by section 1150A alone.
6	Patient Confidentiality	Collecting data at the NDC level may affect patient confidentiality, particularly in areas where few claims are filed.	We disagree with concerns regarding patient confidentiality where there is scarce data available, given the nature of the data to be collected.
7	Confidentiality	Collecting data at the NDC level may reveal sensitive or confidential information, such as discounts for specific drugs.	The data may only be disclosed in the manner and circumstances described in section 1150A(c). We expect that the data will be considered commercial or financial information that is confidential or privileged and is exempt from Freedom of Information Act (FOIA) requests.
8	State Reporting Requirements	A federal collection of this data may conflict or add unnecessary burden to comply with a state reporting requirement.	We are unaware of conflicts with existing state collections. No states submitted comments to raise concerns about conflicts or burden.
9	Burden	The collection require the submission of millions of field of data, which is an unreasonable burden.	We believe the collection is reasonable and necessary in order to collect usable and informative data. The data sought and burden created by the collection is similar to the collection already implemented by the DIR reporting requirement.
10	Burden Estimate Accuracy	The burden estimate does not accurately capture the burden on stakeholders, particularly with regard to the IT system builds or the burden on issuers, who would need to identify the QHPs for the PBMs.	We agree that the burden estimate should reflect burden on QHP issuers. We will revise the burden estimate in the 30-day PRA package to reflect the burden on QHP issuers to identify the QHPs for PBMs and to make modifications to existing IT systems.
11	EDGE Server	HHS must also consider the costs for changes it must make to the EDGE server, which is not authorized for collection of much of the data described in 1150A. Any change to the EDGE server authorizations would require regulatory changes and other significant input from the public.	We disagree with commenters, as this collection is separate and unrelated to current EDGE server collections. We expect that PBMs will need to perform new data extracts to format data already in the possession of PBMs to match the format required for this collection. We have revised the burden statement to factor in this task.
12	MLR Clarification	HHS should clarify the difference between the medical loss ratio (MLR) policy in the 2021 Payment Notice and this collection, or align them, particularly with regard to the definition of "other price concession."	Whether the definition for the MLR policy in the Payment Notice is overly broad is out of scope for this collection.
13	Consistency with DIR	The collection should mirror the DIR reporting requirement to the greatest extent possible.	As stated in the 60 day PRA package, we sought to mirror the DIR reporting requirement to the greatest extent possible (as permitted by 1150A) to minimize burden and ensure consistency across HHS collection efforts.
14	Deregulatory Efforts	The collection is counter to the HHS' goal of reducing regulatory burden.	We recognize the importance of ensuring minimal regulatory burden; however, this collection is required by statute and will provide data that may further the goal of reducing prescription drug costs.
15	Negotiated Price Benchmark	For purposes of reporting price concessions, HHS will need to choose a pricing benchmark against which issuers or PBMs would calculate the amounts paid by manufacturers or pharmacies (or paid to pharmacies). HHS cannot require the reporting of a specific pricing amount without defining it through rulemaking.	We request clarification from the commenter on the requirement for regulating a definition of "negotiated price."
16	Definition Clarifications	Commenters requested clarification whether an independent pharmacy associated with a pharmacy services administrative organization (PSAO) should be classified as a chain pharmacy or an independent pharmacy.	As we are not collecting data by pharmacy type, we decline to clarify whether an independent pharmacy associated with a PSAO should be classified as a chain pharmacy or an independent pharmacy.
17	Other Drug Types	CMS should consider the reporting of biosimilars and interchangeable biologics.	Biosimilars and interchangeable biologics are included in the reporting requirement, as they use NDCs like any other prescription medication.
18	Updates	CMS should update the collection yearly, similar to how the Transparency in Coverage and DIR collections are updated.	The approval for a PRA package is generally for three years, though we anticipate reviewing the collection annually to see if changes are warranted.
19	Attestation	Clarify whether an attestation is required for each QHP issuer or each QHP product.	Under the collection, we will require one attestation for each PBM by QHP issuer. If a PBM administers benefits for more than one QHP issuer, then the PBM will fill out an attestation for each issuer.