

2013 (old version)	2014 (new version)	Type of Change	Reason for Change	Burden Change
Filler (367a)	Blank	Rev	The filler field wasn't being used, so we are deleting it.	No
Filler (367b)	5i Threshold	Rev	The filler field wasn't being used, so we are replacing it with the 5i Threshold field, which is required as part of the Affordable Care Act.	1 hour per reporting period
DESI Indicator (367c)	COD Status and FDA Application Number/OTC Monograph Number	Rev	The DESI Indicator field is no longer relevant to the Medicaid Drug Rebate Program and is being replaced with the new Covered Outpatient Drug Status field and the associated FDA Application Number/OTC Monograph Number field.	One-time burden of 5 hours per labeler
Blank	5i Drug Indicator and 5i Route of Administration (367c)	Rev	In accordance with the Affordable Care Act, the 5i Drug Indicator and 5i Route of Administration fields are being added.	One-time burden of 2.5 hours per labeler
Blank	ACA Baseline AMP (367c)	Rev	In accordance with the Affordable Care Act, the voluntary ACA Baseline AMP is being added.	Negligible because not every labeler will report it, nor will it be reported for every drug
Blank	Reactivation Date	Rev	To ensure more accurate product data reporting and allow labelers to report a date on which a terminated NDC is reintroduced to the market, the voluntary Reactivation Date field is being added.	Negligible because not every labeler will report it, nor will it be reported for every drug

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesignation.

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Blank	Legal Contact Email Address (367d)	Rev	To provide each labeler with the option to submit an alternate email address as part of their reported contact information.	Negligible because not every labeler will report it.
Blank	Invoice Contact Email Address (367d)	Rev	To provide each labeler with the option to submit an alternate email address as part of their reported contact information.	Negligible because not every labeler will report it.

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