Section VI. Significant Questions Remain Regarding Medicare Part D Implementation of the Proposed Rule

We are puzzled as to how the OIG can issue a rule that would completely upend the drug pricing construct in Medicare Part D without any reference or consideration regarding the role of CMS in managing, regulating and overseeing Part D. This is of particular concern because of the large number of Part D regulatory requirements and guidance, including bidding and reporting mechanisms that need to be changed, clarified, or developed, in order to make the new pricing construct viable if the Proposed Rule is finalized. Moreover, some of the issues may have different answers depending on whether the rebate is passed through at POS or is reflected as a discount.

Beyond totally undermining the Part D benefit construct, the Proposed Rule would also completely undo the current drug supply chain with an untested approach that can be expected to result in major costs and burdens to all entities in the supply chain as well as barriers to beneficiary access to drug coverage. Frankly, we just do not see how the chargeback system envisioned is viable under Part D at a time when CMS has no regulatory structure or oversight mechanism applicable to chargebacks. For example, to the extent wholesalers would seek to facilitate such transactions, wholesalers – unlike Part D plans and their PBMs – are not entitled to access enrollee-level data related to costs for Part D and thus would not be able to access the LIS status of the enrollee. We have raised these concerns in other sections of this letter.

Importantly, these CMS programmatic issues must be addressed and resolved prior to the effective date of any safe harbor changes in order to provide the Part D program some level of certainty as to how the program will operate. The potential for major disruption of the program in general, and for beneficiaries in particular, in the absence of duly promulgated regulatory standards with sufficient time for implementation cannot be ignored.

In Table 4 on the next several pages entitled “Medicare Part D Details Needed for Implementation of Proposed Rebate Rule,” we list the key Medicare Part D regulatory requirements (many of which have related subregulatory guidance) that would need to be addressed to make implementation feasible. We further note that this largely needs to be accomplished by duly issued proposed notice and comment rulemaking emanating from CMS, as the delegated entity within HHS to regulate Part D.

Table 4. Medicare Part D Details Needed for Implementation of Proposed Rebate Rule.

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Benefit design	Does the price concession count toward a patient's TrOOP?	42 CFR §. 423.104		
Benefit design	Does the price concession count toward total drug cost?	42 CFR §. 423.104		
Benefit design	Does the price concession count toward negotiated price for purposes of the Coverage Gap Discount Program?	42 CFR §. 423.104		
Benefit design	If price concessions are negotiated at the plan sponsor level, across all plan benefit packages and benefit phases and populations, how would CMS require them to be apportioned to enrollee cost-sharing?	42 CFR §. 423.104		
Benefit design	Can a manufacturer offer different price concessions for the same drug to the same plan sponsor depending on the plan benefit package?	42 CFR §. 423.104		
Benefit design	If a price concession is granted in one benefit phase, must it apply to all benefit phases?	42 CFR §. 423.104		
Benefit design	In the Coverage Gap, what happens to plan payments and enrollee cost-sharing if the price concession exceeds 30%?	42 CFR §. 423.104; 42 CFR § 423.2320		
Benefit design	If price concessions aren't applied uniformly across benefit phases, how will CMS handle straddle claims?	42 CFR § 423.104; 42 CFR § 423.329		
Benefit design	How will pricing be handled for drugs that can be covered under Part B or Part D and are adjudicated using CMS systems (e.g. immunosuppressants for prevention of transplant rejection) or "white bagged"? When covered as Part B, what if Part D cost-sharing would be lower due to price concessions? Could a beneficiary appeal?	42 CFR § 423.104; 42 CFR § 423.566		
Benefit design	How does the price concession reduce cost-sharing if the enrollee has a copay for preferred brand drugs?	42 CFR § 423.104		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Benefit design	What cost-sharing should a plan assess for drugs where the total price concessions bring the net cost of a drug to or below $0.00? For example, if the rebate passed through at the point of sale is larger than beneficiary coinsurance, because of the manufacturer discount that is also provided in the Coverage Gap?	42 CFR § 423.104		
Benefit design	Many vaccines are covered by Part D plans. Does the change in safe harbors apply to vaccines? Many plans include them on $0 tiers (especially the USPSTF endorsed preventive services vaccines). How could a price concession be "passed through" when the cost-sharing is already $0?	42 CFR § 423.104		
Benefit design	Since risk adjustments are used to calculate the bid amounts, will CMS recalibrate the RxHCC model to reflect the new applicable costs associated with high-rebate versus low-rebate classes?	42 CFR § 423.265		
Benefit design/LIS	What if LIS enrollee is in the copay phase of benefit?	42 CFR § 423.782		
Benefit design/LIS	What if tier is $0 for an LIS enrollee? (e.g. a biosimilar on the preferred drug tier)	42 CFR § 423.782		
Benefit design/LIS	What if LIS enrollee is in the $0 cost-sharing benefit phase?	42 CFR § 423.782		
Benefit design/LIS	Will the de minimis premium policy for LIS be increased for 2020? This may be critical to avoid massive plan disruption for LIS enrollees.	42 CFR § 423.782		
Beneficiary design – different types of pharmacies	The rule discusses pharmacies only in general terms but the application of the rule to various kinds of pharmacies is complicated – LTC, mail order, specialty will have different applications and expectations.	42 CFR § 423.120 42 CFR § 423.124		
Beneficiary rights	How would CMS expect plans to apply tiering exceptions policies? Would the percentage price concession applied to the lower-tier drug be applied to the higher-tier drug's price?	42 CFR § 423.578		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Beneficiary rights	How would CMS expect plans to apply formulary exceptions when approving a no price concession drug?	42 CFR § 423.578		
Beneficiary rights	What are beneficiary appeal rights, if any, regarding the amount of rebate they receive?	42 CFR § 423.566		
Beneficiary rights	How will CMS handle transition fills given the likelihood of significant formulary changes and enrollment changes for the first year this is in effect?	42 CFR § 423.120(b)(3)		
Bid process	If price concessions are negotiated at the plan sponsor level, rather than the plan benefit package level, how would CMS require them to be allocated in the bid?	42 CFR § 423.265		
Bid process	What is the timing for updating the Bid Pricing Tool to accommodate these changes to price concessions?	42 CFR § 423.265		
Bid process	How would CMS handle OOPC tool and Total Beneficiary Cost revisions?	42 CFR § 423.265		
Bid process	How will changes in Part D bid amounts be incorporated into MA-PD submissions?	42 CFR § 423.265 42 CFR § 422.254		
Bid process	Would CMS require other plan types (e.g. EGWPs) to follow its lead on the above topics?	42 CFR § 423.265		
Data reporting	Will there be changes to the PDE record? How will claims be reported where a rebate was provided?	Medicare Part D Reporting Requirements		
Data reporting	What is the effect on PDE data reporting procedures? Would the price concession be reported on the estimated rebate field?	Medicare Part D Reporting Requirements		
Data reporting	Since only plan sponsors have all the data to submit PDEs (and PDEs are the basis for the Coverage Gap Discount Program), how will PDEs be reported when wholesalers are involved?	Medicare Part D Reporting Requirements		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Data reporting	How are claims to be reported where a rebate was provided but the script was later determined not to be eligible for a rebate (e.g., due to 340B, denial, patient recoupment, duplicate claims)?	Medicare Part D Reporting Requirements		
Data reporting	How will these price concessions be reflected in DIR reports and how will CMS revise DIR reporting procedures to account for these price concessions? And, how will the reporting requirements be revised to account for the new requirements for PBM service fees?	42 CFR § 423.352; 42 CFR § 423.360		
Data reporting	Would existing NCPDP reporting mechanisms be able to accommodate these changes?	NCPDP Reporting Standards		
Data reporting	Would CMS need to create a manufacturer agreement since confidential data is being collected and reported?	42 CFR § 423.322		
Definitions	Will CMS adopt the same definitions as OIG? What is the definition of a rebated or discounted drug? How will the definition of 100% rebate at POS accommodate those drugs that are rebatable but are then subject to retroactive denial due to a range of reasons (e.g., due to 340B, patient recoupment, duplicative claims)? What is the definition of negotiated price for rebated drugs or discounted drugs? What is the definition of a chargeback?	42 CFR § 423.100; 42 CFR § 423.308		
Enrollee communications	What price is to be reported on Medicare Plan Finder (MPF)? How often will prices be required to be updated?	TBD		
Enrollee communications	What price is reported on the Explanation of Benefits (EOB)?	42 CFR § 423.128		
Enrollee communications	What price is to be reported on the forthcoming Real Time Benefit Tool (RTBT)?	TBD		
Enrollee communications	What changes will be required by CMS in terms of the language in the Evidence of Coverage (EOC) and model marketing materials?	42 CFR § 423.128		
Enrollee communications	Will enrollees be told the price concession amount at POS? What if a plan uses both rebates passed through at POS and discounts?	42 CFR § 423.128; 42 CFR § 423.132		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Enrollee communications	Would the plan Advanced Notice of Changes (ANOC) have to be revised for 2020 (and annually thereafter) to reflect changes in the rebate status?	42 CFR § 423.128		
Formulary structure	Will the CMS formulary review process change? If a plan has both rebated drugs and discounted drugs (in lieu of rebates) is that to be reflected in the formulary?	42 CFR § 423.272		
Formulary structure	Can rebated drugs be placed on their own tier? Will additional tiers be allowed to accommodate the new arrangements?	42 CFR § 423.104; 42 CFR § 423.272		
Formulary structure	If a manufacturer's price concession takes the form of alternative NDCs for existing products, how will CMS adopt formulary flexibility to allow for this?	TBD		
Formulary structure	If instead of rebates or discounts, a manufacturer provides the same drug but gives it a new NDC, or offers it as an authorized generic, or an authorized biosimilar, or some other alternative category, how is such option treated under the formulary? E.g., can a plan meet the two drugs per category/class by offering a rebated drug with POS pass-through and the same drug with a different NDC?	TBD		
Other Part D requirements – MLR	How will the significant new costs (e.g., to update systems, update contracts, staff call centers) be included for purposes of administrative costs for purposes of MLR compliance? In order to meet the targets, plans will have to collect significantly higher premiums and make larger than expected claims payments, driving up enrollee and taxpayer costs if there isn't an exception for these new costs.	42 CFR § 423.2420		
Other Part D requirements – MTM	How would the price concession or reduction be accounted for in the cost component of MTM? Might previously-qualified enrollees no longer qualify as they no longer meet the cost-threshold?	42 CFR § 423.153		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Other Part D requirements – prompt pay	Will payments to pharmacies still be subject to prompt pay? How will that work with regard to chargeback payments where CMS has no regulatory authority over wholesalers?	42 CFR § 423.520		
Other Part D requirements – star ratings	For appeals and exceptions, will CMS handle beneficiary complaints in such a way that plan quality ratings are not affected? (E.g., enrollee thinks rebate should be higher, but it isn't)	42 CFR § 423.186		
Other Part D requirements – transition fill	How will the price concessions or reductions be applied to transition fills?	42 CFR § 423.120		
Reconciliation	Use of projected price concessions on market share – what if not achieved?	42 CFR § 423.343		
Reconciliation	How will the price concessions be reported for purposes of reconciliation?	42 CFR § 423.343		
Reconciliation	Will CMS create a process to reconcile over- or under-payments of price concessions to enrollees?	42 CFR § 423.343		
Risk score model	When and how will CMS recalibrate the RxHCC model to reflect these changes? If there is meaningful selection bias (e.g., all Hep C beneficiaries enroll in the same plan), how will the model compensate for that?	42 CFR § 423.265		
Administrative burden	What of the above needs to go through PRA processes, notice-and-comment rulemaking versus guidance, or other formal mechanisms?	TBD		
Attestation	Plan sponsors are required to certify the accuracy, completeness and truthfulness of all data. Without complete, detailed and workable guidance on every facet of this undertaking, plan sponsors will not be able to make these certifications. CMS must provide an alternative good faith compliance approach as the standard one is not viable for the foreseeable future.	42 CFR § 423.265		