Part D Data Regulation
Side-by-Side Comparison of the Proposed and Final Rule

Entity	NPRM	FINAL RULE
Summary	CMS proposed broad access to the use of claims data in the NPRM under the same terms and protections as Parts A and B information (i.e., minimum necessary data, subject to a DUA, for legitimate research purposes). In doing so, the Secretary had flexibility when adopting the final rule, to either implement a rule allowing broad access to the use of claims data, or to adopt a more restrictive rule.	The rule is limited to the original 37 PDE elements specified in 2006 and 2007. Release of these elements outside of CMS must be in accordance with our minimum necessary policy and CMS data sharing procedures, with some additional protections that include the encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors.
CMS	Under the proposed rule, CMS and its contractors would have access to all PDE elements.	Under the final rule, CMS and its contractors have access to the original 37 PDE elements for non-payment purposes.
Other Federal Agencies	CMS proposed to allow claims data to be released under the same terms and protections as Parts A and B information is released today. CMS requested comment on how to best serve the needs of other agencies through the sharing of information while at the same time addressing the legitimate concerns of the public and of Part D plans that we guard against potential misuse of the data.	In addition to the minimum necessary data policy, we added additional protections that in some cases limit the data elements provided to government agencies. In identifying these protections, CMS distinguishes between HHS and Congressional Oversight agencies versus other non-HHS government agencies. The main distinction is that HHS and Congressional oversight agencies would have access to disaggregated drug cost elements (such as ingredient cost and dispensing fee) if needed, whereas non-HHS government agencies would not have such access. We provide for State access to claims data for care coordination purposes.
External Entities[1]	CMS proposed to allow claims data to be released under the same terms and protections as Parts A and B information is released today. CMS asked for comment on whether CMS should consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research, commercial purposes, or to ensure that propriety plan data or confidential beneficiary data are not released.	Under the final rule, external entities have access to the minimum necessary data for research purposes subject to additional protections such as the encryption of beneficiary, prescriber, and pharmacy identifiers unless needed to link to another data set. In addition, external entities will not have access to plan identifiers or disaggregated drug cost data that breaks out drug ingredient cost or dispensing fees. CMS does not release data for commercial purposes.

[1]Under the final rule, an external entity does not include States, executive branch governmental agencies, or Congressional oversight agencies. The Congressional oversight agencies are defined as: the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when acting on behalf of a congressional committee in accordance with 2 U.S.C. § 166(d)(1).