

#	Common Theme	Commenters																												Summary of Comment	Proposed Responses								
		Academy of Physicians in Clinical Research	AMA	Association of General Internists	American Association of Clinical Endocrinologists	American Academy of Dermatology Association	American Academy of Physical Medicine and Rehabilitation	American Association of Neurological Surgeons and Congress of Neurological Surgeons	American Association of Orthopedic Surgeons	American College of Cardiology	American College of Emergency Physicians	American College of Physicians	American Medical Association	American Osteopathic Association	American Otolaryngological Association	American Podiatric Medical Association	Association of American Medical Colleges	Association of American Medical Colleges	Association of Clinical Research Professionals	ACRE Coalition	Johns Hopkins Medicine	Kaiser	Massachusetts Medical Society	MDA	Medical Group Management Association	Medical Society of New Jersey	Pfizer	PPMA	Primera			Ridgers, NJ	Ridgers, NJ	TriCare	United Therapeutics	Various Individuals (Arlington, MD, Lincoln, MD, Wren, MD, Smith, Burton)			
1	Unilateral dismissal of disputes			X		X	X	X	X	X	X	X	X	X	X	X	X	X	X				X	X	X	X											Many commenters were concerned with whether manufacturers would be allowed to unilaterally dismiss disputes. Commenters pointed out the proposed language to manufacturers to be provided after a dispute is initiated states that "you may resolve the dispute by submitting and attesting to the corrected data. After reviewing the disputed information, you may dismiss the dispute or request that physician or teaching hospital who initiated the dispute to withdraw it." Commenters stated that unilateral dismissals by the manufacturer are contrary to the final rule, which provides that the parties to the dispute may and should continue to work to reach resolution, but that this data would be marked as "in dispute" until an agreement is reached.	We appreciate and agree with the comments that manufacturers should not unilaterally dismiss disputes that the physician does not consider resolved. We believe that all disputes should be resolved as described in the final rule whereby our system is reported the results of that resolution process. We believe that the terminology describing the system functionality made available to applicable manufacturers and applicable GPOs, mischaracterizes the opportunity to report that the dispute has been resolved in accordance with the rule. As a result, we are clarifying the language presented in the system to illustrate our stance that compliance with the final rule's description of how disputes shall be resolved predicates the use of the system functionality provided. Any dispute that is unresolved will be posted on the public website, yet marked as "disputed" in accordance with § 403.906(g)(4)(ii).	
2	Attestation clause or penalty for physicians for bad faith disputes																													X						The commenters suggested that physicians should have an attestation clause as well, or penalties for bad faith disputes.	We appreciate the comments, but we do not have the authority to require physicians to attest to their dispute or subject physicians to civil monetary penalties for bad faith disputes.		
3	Limit the number of disputes initiated																								X							X					Commenters suggested limiting the period for dispute or the number of times a dispute can be initiated.	We appreciate the comment, but we do not have the authority to limit the number of times a record may be disputed. Section 1128G(c)(1)(D) of the Social Security Act requires that CMS provide a review/dispute and correction period of "not less than 45 days", and we are providing a 45-day review and additional 15 day correction period.	
4	Physician reputation implications					X	X	X						X				X						X		X											Some commenters pointed out that physicians bear the risk of potential employment and reputational implications due to improper dismissals and incorrect data.	We appreciate the comments and are sympathetic to the possibility of reputational implications to physicians. However, Section 1128G(c)(1)(D) of the Social Security Act requires that CMS provide a review and correction period of "not less than 45 days", and we are providing a 45-day review and additional 15 day correction period. Physicians will have the time required to work with applicable manufacturers and group purchasing organizations to resolve any incorrect data.	
5	Calendar year dispute limitation			X	X								X											X	X								X				Commenters were also concerned about the inability to initiate a dispute after a calendar year. Other commenters supported the calendar year limitation.	We appreciate the comments, but we do not have the authority to alter the existing calendar year dispute limitation.	
6	Extend/Maintain 45 day review window	X	X	X		X		X	X							X	X				X	X						X	X	X	X						Many commenters thought the 45-day dispute period was too short for physicians to review the data and initiate a dispute. The commenters noted the busy schedules of physicians and the burden it places on them to review the data. Other commenters disagreed that the 45-day review period was too short.	We appreciate the comments and are sympathetic to the need to provide time for review and correction and tried to maximize the time as much as possible. Section 1128G(c)(1)(D) of the Social Security Act requires that CMS provide a review and correction period of "not less than 45 days", and we are providing a 45-day review and additional 15 day correction period. In order to meet the other statutorily mandated deadlines, we do not believe that additional time may be granted in this first year of the Open Payments program.	
7	Postpone public reporting by 6 months					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X													X			Numerous commenters were concerned with the implementation timeline and the September 30, 2014 publication date. These commenters suggested that the date be pushed back 60 days. Other commenters supported the current timeline, noting that while the dispute resolution process is important, this should not interfere with or delay the timely release of physician payments data to the public.	We appreciate the comments, but we do not have the authority to alter the publication date.
8	Need for education and outreach															X											X	X						X			Commenters noted the need for increased education due to the confusion on the registration and dispute process, as well as additional time to register. Some commenters pointed out that the physician registration date was pushed back from January 1 to June 1, 2014, not allowing adequate time for physician registration. Commenters worried that there is not enough time for outreach to physicians. One commenter suggested providing more explanatory materials to physicians to assist in their review.	We appreciate the comments and agree that additional outreach and education resources should be made available to both physicians and applicable manufacturers and GPOs. We will provide periodic updates to education material on our website and through our listserv.	

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20	Association plans to instruct clinical research physicians to not resolve disputes	A few commenters noted that they will recommend to clinical research physicians to not resolve disputes, but instead mark incorrect data as "in dispute" and "leave it at that".	Thank you for your comment. This suggestion is outside the scope of PRA.
21	Concerns with the registration process for authorized representatives and officials	One commenter objected to the registration process requiring Authorized Officials and Authorized Representatives to provide personal information during registration. Additionally, the commenter requested information on how authorized representatives residing outside the United States should complete the registration process for Phase Two.	Thank you for your comment. This suggestion is outside the scope of PRA.
22	Attestation agreement concerns	One commenter objected to the requirement that an Authorized Official attest to five series of statements, when only one of the fields is contemplated by the final rule. Another commenter suggested that the attestation clause be excluded as a requirement for transactions that are in dispute.	Thank you for your comment. This suggestion is outside the scope of PRA.
23	Incorrect data due to system	One commenter requested the ability to report incorrect data due to database error, through no fault of the manufacturer.	Thank you for your comment. If an error submission is found, the manufacturer is able to submit a correction to the data at anytime. If a physician notices an error, the manufacturer and the physician should work together to submit the appropriate correction.
24	Privacy concerns for physicians	One commenter requested that CMS identifies the information that will be disclosed to the public so that physicians can take steps can minimize identity theft risks. The commenter also inquired whether there are special safeguards for physicians who have been the victim of identity theft. The commenter suggested that the website contain notices clarifying that physicians should minimize the amount of information they disclose.	Thank you for your comment. Comments regarding data disclosed during the physician registration process is outside the scope of PRA.
25	Ability for manufacturers to designate a dispute resolution and correction contact person	One commenter requested that CMS allow applicable manufacturers to designate within the system an individual or individuals to serve as the dispute resolution and corrections contact person.	Thank you for your comment. We will consider future system enhancement which will introduce a new user role for the manufacturers to designate a point of contact for dispute and resolution and correction. In the interim, CMS has provided clear instructions to manufacturers about which system role will be receiving dispute notifications from the system.
26	Encourage covered recipients to initiate disputes using the system vs. calling applicable manufacturers directly	One commenter requested that CMS encourage covered recipients to initiate disputes using the system vs. contacting the manufacturer directly. Another commenter disagreed, recommending that CMS encourage manufacturers and GPOs to offer covered recipients the opportunity to review payment data before the data is submitted to CMS.	Thank you for your comment. CMS plans to include clear direction to covered recipient on how they can initiate a dispute using the system. We will also stress that any disputes initiated outside of the system will not be tracked by CMS.
27	Instances may occur when there is no resolution to a dispute	One commenter requested that CMS acknowledge that there are certain disputes for which resolution may not be possible.	Thank you for your comment. This suggestion is outside the scope of PRA.
28	Ability for covered recipients to submit a comment on a record without submitting a dispute.	One commenter requested that CMS reconsider the functionality to comment on records that are not being disputed.	Thank you for your comment. We will consider this as a potential system enhancement in the future.
29	Ability for manufacturers to filter for records with disputes	One commenter requested that CMS allow the System to enable manufacturers to filter for records with disputes versus records with comments, so they can be managed with the appropriate priority.	Thank you for your comment. We will consider this as a potential system enhancement in the future.
30	Ability for manufacturers to flag a record as "resolved"	One commenter requested that the System allow manufacturers to flag a record as "resolved", if direct contact with a recipient results in a mutual resolution and the recipient does not resolve the record on their end. One commenter also requested to enable a manufacturer to mark a resolved dispute as "resolved with no recipient response".	Thank you for your comment. We expect that all disputes that are resolved, regardless of the mechanism in which those resolutions are reflected within the as "resolved" be done in accordance with the guidance provided within the final rule.
31	Revisit term "dismissed"	One commenter requested that the System replace existing "dismissed" term with "resolved- with no change", "resolved- with change", "requested for withdrawal", etc.	Thank you for your comment. We have addressed this issue in response to other comments received through this public solicitation.
32	Perform quarterly data updates	One commenter suggested that CMS conduct quarterly data refresh updates.	Thank you for your comment. This suggestion is outside the scope of PRA.
33	Resolution of disputes is not required	One commenter suggested that CMS educate covered recipients that dispute resolution is not required.	We appreciate the comment. This policy is outside the scope of this PRA solicitation.