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# Common Theme	cademy of Physicians in Clinical Research StaMed	ggregate Syend Alliance merican Association of Clinical Endocrinologists	merican Ac ademy of Dermatology Association	merican Academy of Physical Medicine and Rehabilitation	merican Association of Neurobigical Surgeons and Congress of Neurological Process	merican Association of Orthop aedic Surgeon's merican College of Cardiology	merican College of Emergency Physicians	merican College of Ptyrsicians merican Medical Association	merican Optometric Association	merican Ostoopathic Association Trerican Podiatric Medical Association	merkan Urokogical Association	ss ociation of American Medical Colleges s ociation of Clinic al Research Professionals	ME Califièn	bins Hopkins Medicine evus	Tassachusetts Medical Society	redchi The Maryland State Medical Society	records a outproversegration according to the second second records of the second second records of the second sec	ew Charitable Trust bee	16MA	rimacea Atoors. NJ	utgers, NJ	rienzwn Organiation	para-annun wious indhriduals (Applebaum, MD, Leachin, MD, Wen, MD, Smith, Burton)	Summary of Comment Proposed Reponses
1 Unilateral dismissal of disputes	40			X	X	X X	X	XX	X	w w	An	X X	CM	<u>10</u>	X	X	× X	pe	44	Pri Ru	Ru	Ur.	00 Na	Many commenters were concerned with whether manufacturers would be allowed to unilaterally dismiss disputes. Commenters pointed out the proposed Janguage to manufacturers to be provided fairer a dispute is initiated states that 'you any the dispute by mation, international to the four or equest that 'you any the dispute by mation, international to the four or equest that 'you any the dispute by mation, international to the dispute may and the dispute should be resolved as described in the final rule whereby unilateral dismissals by the manufacturer are contrary to the final rule, which resolution, but that this data would be marked as "in dispute" until an agreement is reached.
2 Attestation clause or penalty for physicians for bad faith disputes																		×						The commenters suggested that physicians should have an attestation clause as well, We appreciate the comments, but we do not have the authority to require physici or penalties for bad faith disputes. It to their dispute or subject physicians to civil monetary penalties for bad faith disputes.
3 Limit the number of disputes initiated																,	(Х	:				<	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 A requires that CMS provide a review/dispute and correction period of "not less that AS 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 We appreciate the comments and are sympathetic to the possibility of reputational implications due to improper dismissals and incorrect data. Implications to physicians. However, Section 1285(c)(110) of the Social Security requires that CMS approvale a review and correction period of "not less than 45 day 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		×		х				x							x	x						2	<	Commenters were also concerned about the inability to initiate a dispute after a calendar year. Other commenters supported the calendar year limitation.
6 Extend/Maintain 45 day review window	y x	*	x		x	x	x			xx			x	x		,	(xx	x	X		Many commenters thought the 45-day dispute period was too short for physicians to review the data and initate a dispute. The commenters noted the busy schedules of physicians and the burden tip laces on them to review the data. Other commenters disagreed that the 45-day review period was too short. Intersection period of not less than 45 days, and we are providing a 45-day review and disagreed that the 45-day review period was too short. Intersection 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	Numerous commenters were concerned with the implementation timeline and the September 30, 2014 publication date. These commenters suggested that the date be publication date. Subject 40 days. Other commenters suggested that the date be publication date. While the disputer resolution process is important, this should not interfere with or delay the timely release of physician payments data to the public.
8 Need for education and outreach	1					xx	x			x						,	K X					:	ĸ	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.

Open Payments Review of PRA Comments - June 2014		
Common Theme C	A loos clark or of Christ and K. Jurgeon and K. Jur	Summary of Comment Proposed Reponses
Require details from X X	American Ame	several commenters suggested that the "reason for dispute" comment field should We appreciate the comments and note that the system as designed requires
physician when dispute is initiated		e required for every disputed record. One commenter recommended that CMS provide a list of potential reasons to select from. Another commenter suggested that the system allow the covered recipient to complete / aut Hill various points about the decord which it is disputing. Another commenter act and dispute work and the physicians to provide a list of the information meeded in order to assist the manufacturer in investigating and resolving the dispute. The dispute, including the parameter suggested assist the manufacturer in investigating and resolving the dispute. Sustain that are that are and sense work and the anount of the assist the anount should be commenter suggested that the physican be formide to dispute accurate. One commenter suggested that the physican be limited to disputing only the date and the anount of the payment or transfer of value. One commenter also suggested to provide recipients with a list of potential reasons to select from for the portion of the data that is being disputed.
10 Inquiry into how data X X X X X X will be presented on public site		Several commenters recommended that data not be published if it is in dispute by ooth parties. Another comments resugested separating the data into undisputed data on banked as 'under review'' instead of 'disputed''. One commenter recommended that payments be marked as 'under review'' instead of 'disputed''. One commenter suggested that here be clear language that explains the meaningful context of disputed versus undisputed data. Another commenter questioned the difference between 'affirming' a payment or other transfer of value and doing nothing (not disputing).
11 Physician dispute rate		A commenter recommended that the physician dispute rate be tracked as well, imilar to the manufacturer dispute rate. Another commenter suggested that the hysician value should be listed along with the manufacturer's for unresolved
12 Inquiry into how X X X X X S Sent for dispute actions		Jisputes. Thank you for the comment: The system as designed will notify manufacturers by commenters suggested that the system notify the manufacturer by email when a dispute has been initiated, or withdrawn. The system will notify mmediately when a dispute is marked. Commenters also requested that the physician by email when the dispute has been acknowledged as well as resolved. However, in order to be notified of any activity in the Open Payments system, physicians must be registered in the physicians must be registered in the Open Payments system.
13 Set dollar limit for disputes that are reported		Commenters recommended that low (de minimis) data that is disputed not be ublished as disputed. The commenters were concerned that items of such low value stated in the final rule, "we intend to monitor the volume and terms of disputes and would be too costly for the manufacture to properly investigate and resolve, and would lead to all de minimis data being published as disputed.
14 Provide graphical user X interface (GUI) and data		One commenter requested that both graphical user interface (GUI) and data import nethods be available for data submission. Thank you for your comment. This suggestion is outside the scope of PRA; however, the system as designed allows both GUI and data import methods for data
import methods 15 Allow research institutions ability to register		A commenter requested that research institutions be allowed to review and dispute thank you for your comment. This question is outside the scope of PRA since research payments or other transfers of value made indirectly to covered recipients wherein the research institutions is the initial recipient.
16 Redundant system for registration		One commenter did not like that the new system requests many fields of information or order to register which has already been requested by other CMS registration systems. The commenter suggests integrating with other CMS systems in order to make registration simpler.
17 Ablifty to dispute all data with one comment:		A commenter was concerned that a physician may choose to dispute one, multiple, or all records reported by completing one comment box. If a comment and agree that physicians submitting comments on multiple disputes should ensure the comment field is populated so that they may provide applicable manufacturers and group purchasing organization with enough information to research the dispute. (We will consider future enhancements that will allow the user to confirm that they want the completed comment box to be transmitted to one applicable manufacturer and group purchasing organization or multiple entities.
18 CMS to provide 3rd X X X		A commenter suggested that CMS should provide a third party adjudicator to the dispute resolution process. Another commenter stated that only the actual physican ra relevant representative affiltated with a teaching hospital should be able to nitiate and resolve disputes in the System. Another commenter stated that CMS implement an arbitration process in place to ensure resolution is reached by the manufacturer and covered recipicient. That was used for the comment. As stated in the final rule, we maintain that we (CMS) the actively engaged in mediating dispute resolutions and believe that the relationship exists between the manufacturer and covered recipicient. That was used in the final rule, we maintain that we (CMS) the actively engaged in mediating dispute resolutions and believe that the relationship exists between the manufacturer and covered recipicient. That was used to active the actively engaged in mediating dispute resolutions and believe that the relationship exists between the manufacturer and covered recipicient. That was used to active the actively engaged in mediating dispute resolutions and believe that the relationship exists between the manufacturer and covered recipicient.
19 Allow atternate staff to perform review & dispute X	S S S S S S S S S S S S S S S S S S S	Comments requested that physicians be allowed to designate a third party to apther and dispute information on the website. Another commenter questioned whether the authorized representative. The physician covered recipient will be vetted by our system.

en Payments iew of PRA Comments - June 2014																								
Common Theme	ademy of Physicians in Clinical Research valved	gregate Spend Alliance rerican Association of Clinical Endocrinologists	rerican Academy of Dermatology Association	terican Academy of Physical Medicine and Rehabilitation action Academy of Narrobain Academical Screeness and Promoses of Narrobained	iercan Association of Neuro Digcar Surgeons and Longress of Neuro Ropical geons rerien Association of Orthonaedie Surgeons	ter ream reasonances en en entre mente entre processes entre process entre processes entre processe entre processes entre processe	terican College of Emergency Physicians	terican College of Physicians rerican Medical Association	terican Optometric Association	terican Osteopathic Ass odation erican Podiatric Medical Association	rerican Urological Association	codation of American Medical Colleges octation of Clinics of Bosococh Boole strends	ocuation of Carry, and execution Protos socials	ins Hopkins Medicine vus	iosachurietts Medical Society	odDri The Manyland State Medical Society Sical Group Management Association	dical Society of New Jersey	w Charitable Trust ter	84/A	macea tores MI	active to a construction of the construction o	krown Organiation	shee-Smith down build additional American American American American American Brussand	Summary of Comment Proposed Reponses
Association plans to instruct clinical research physicians to not resolve disputes	X	24 14	4u	un an		5	-vy	4	An	4	An	3 3	X	0 3	W	<u>×</u> ×	Ŵ		4	4		5	10 CE	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".
Concerns with the registration process for authorized representatives and officials																			x					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.
Attestation agreement concerns																			x				x	One commenter objected to the requirement that an Authorized Official attest to five Thank you for your comment. This suggestion is outside the scope of PRA. 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.
Incorrect data due to system								x							x									One commenter requested the ability to report incorrect data due to database error, Thank you for your comment. If an error submission is found, the manufactur through no fault of the manufacturer. Bable to submit a correction to the data at anytime. If a physician notices an en manufacturer and the physician should work together to submit the appropri correction.
Privacy concerns for physicians								x							x									One commenter requested that CMS identifies the information that will be disclosed to the public so that physicians can take steps can minimize identity thetr 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.
Ability for manufacturers to designate a dispute resolution and correction contact person	x																							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 periosn. The interim, CMS has provided instructions to manufacturers about which system role will be receiving disput notifications from the system.
Encourage covered recipients to initiate disputes using the system vs. calling applicable manufacturers directly	x																	x						One commenter requested that CMS encourage covered recipients to initiate disputes using the system vs. contacting the manufacturer and precipient on how they can initiate a dispute using the system. We will also st commenter disputes initiated outside of the system will not be tracked by CMS. to offer covered recipients the opportunity to review payment data before the data is submitted to CMS.
Instances may occur when there is no resolution to a dispute	x																							One commenter requested that CMS acknowledge that there are certain disputes for Thank you for your comment. This suggestion is outside the scope of PRA. which resolution may not be possible.
Ability for covered recipients to submit a comment on a record without submitting a dispute.		x																						One commenter requested that CMS reconsider the functionalility 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.
Ability for manufacturers to filter for records with disputes		х																						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.
Ability for manufacturers to flag a record as "resolved"		x																						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".
Revisit term "dismissed"		x							Π						Π			x						One commenter requested that the System replace existing "dismissed" term with "resolved- with no change", "resolved- with change", "requested for withdrawal", etc.
Perform quarterly data updates																		x						One commenter suggested that CMS conduct quarterly data refresh updates. Thank you for your comment. This suggestion is outside the scope of PRA.
Resolution of disputes is not required															1				X			Ιſ		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 soli