

nutrition would continue for as long as medical necessity and Part B coverage continues and the bid limits would be based on the average monthly costs per beneficiary for the bundle of items and services. We are soliciting comments on the following list of questions regarding proposals we may make to change the payment rules and other rules for DME and enteral nutrition under the DMEPOS competitive bidding program.

- Are lump sum purchases and capped rental payment rules for DME and enteral nutrition equipment that were implemented to prevent prolonged rental payments still needed now that monthly payment amounts can be established under competitive bidding programs for furnishing everything the beneficiary needs each month related to the covered DME item or enteral nutrition?
- Are there reasons why beneficiaries need to own expensive DME or enteral nutrition equipment rather than use such equipment as needed on a continuous monthly basis?
- Would there be any negative impacts associated with continuous bundled monthly payments for enteral nutrients, supplies, and equipment or for certain DME? If so, please explain.
- Certain DME items such as speech generating devices and specialized wheelchairs may be adjusted or personalized to address individual patient needs. Would payment on a bundled, continuous rental basis adversely impact access to these items and services? If so, please provide a detailed explanation regarding how this method of payment would create a negative impact on access to these items and services or other items and services currently subject to competitive bidding.
- If payment on a capped rental, rentto-own basis or lump sum purchase basis is maintained for certain items under the competitive bidding program, should a requirement be added to the regulations specifying that the supplier that transfers title to the equipment to the beneficiary is responsible for all maintenance and servicing of the beneficiary-owned equipment for the remainder of the equipment's reasonable useful lifetime with no additional payment for these services? The cost of such a mandatory supplier warranty would be factored into the bids submitted by the suppliers and the payment amounts established based on the bids for the items. If such a requirement was established, should the term maintenance and servicing be defined to include all necessary maintenance, servicing and repairs that are currently paid for separately under

the Medicare program in addition to any additional adjustments or personalization of the equipment that may be needed once title transfers to the patient? We believe these requirements may be necessary to safeguard the beneficiary and access to necessary services related to beneficiary-owned DME.

- Would payment on a bundled, continuous rental basis for certain items adversely impact the beneficiary's ability to direct their own care, follow a plan of care outlined by a physician, nurse practitioner or other medical provider (for example, occupational, physical or speech therapist), or provide for appropriate care transitions? If so, please explain.
- What are the advantages or disadvantages for beneficiaries and suppliers of bundled bidding and payments for enteral nutrients, supplies, and equipment or DME?
- Should competitive bidding programs utilizing bundled payments be established throughout the entire United States so that all beneficiaries are included under programs where suppliers have an obligation to furnish covered items and all related items and services?
- Is a continuous bundled monthly payment used by commercial payers or State Medicaid programs for enteral nutrients, supplies, and DME and do these approaches inform this potential new payment arrangement for Medicare.

Dated: January 31, 2014.

Marilyn Tavenner,

 $Administrator, Centers \ for \ Medicare \ \mathcal{C} \\ Medicaid \ Services.$

Approved: February 4, 2014.

Kathleen Sebelius,

 $Secretary, Department\ of\ Health\ and\ Human\ Services.$

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DEPARTMENT OF HOMELAND SECURITY

6 CFR Chapter I

8 CFR Chapter I

19 CFR Chapter I

33 CFR Chapter I

44 CFR Chapter I

46 CFR Chapters I and III

49 CFR Chapter XII

[Docket No. DHS-2014-0006]

Retrospective Review of Existing Regulations; Request for Public Input

AGENCY: Office of the General Counsel, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Department of Homeland Security (Department or DHS) is seeking comments from the public on specific existing significant DHS rules that the Department should consider as candidates for modification, streamlining, expansion, or repeal. These efforts will help DHS ensure that its regulations contain necessary, properly tailored, and up-to-date requirements that effectively achieve regulatory objectives without imposing unwarranted costs.

DHS is seeking this input pursuant to the process identified in DHS's Final Plan for the Retrospective Review of Existing Regulations. According to the Final Plan, DHS will initiate its retrospective review process, on a three-year cycle, by seeking input from the public. The most helpful input will identify specific regulations and include actionable data supporting the nomination of specific regulations for retrospective review.

DATES: Written comments are requested on or before March 28, 2014. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may submit comments, identified by docket number DHS—2014—0006, through the Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT:

Charlotte Skey, Senior Regulatory Economist, Office of the General Counsel, U.S. Department of Homeland Security. Email: Regulatory.Review@ dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to comment on this notice by submitting written data, views, or arguments using the method identified in the **ADDRESSES** section.

Instructions: All submissions must include the agency name and docket number for this notice. All comments received will be posted without change to http://www.regulations.gov.

Docket: For access to the docket to read background documents or comments, go to http://www.regulations.gov.

II. Background

On January 18, 2011, the President issued Executive Order 13563, "Improving Regulation and Regulatory Review," to ensure that Federal regulations seek more affordable, less intrusive means to achieve policy goals and that agencies give careful consideration to the benefits and costs of those regulations. 76 FR 3821. The Executive Order required each Executive Branch agency to develop a preliminary plan to periodically review its existing regulations to determine whether any regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving its regulatory objectives.

DHS's approach to conducting retrospective review focuses on public openness and transparency and on the critical role of public input in conducting retrospective review. To that end, DHS published a notice and request for comments in the Federal Register on March 14, 2011. 76 FR 13526. In that notice, DHS solicited public input on how DHS should structure its retrospective review and which DHS rules would benefit from retrospective review. On June 6, 2011, DHS published a notice of availability; request for comments announcing the availability and seeking comment on its Preliminary Plan for the Retrospective Review of Existing Regulations. 76 FR 32331. DHS considered this public input as it developed a Final Plan.

On August 22, 2011, DHS issued its Final Plan for the Retrospective Review of Existing Regulations (Final Plan or DHS Final Plan). The DHS Final Plan is available online at http://www.dhs.gov/xlibrary/assets/dhs-ogc-final-retrospective-review-plan-8-22-11-final.pdf. The Final Plan established a process for identifying regulations that may be obsolete, unnecessary, unjustified, excessively burdensome, or counterproductive. Under the Final

Plan, DHS (and/or a DHS component) will publish a notice in the Federal Register every three years seeking public input regarding the regulations that should be subject to retrospective review. The previous Federal Register notice from DHS seeking such public input was published in 2011. 76 FR 13526. The notice published today in the Federal Register requesting nominations for additional regulations that should be subject to retrospective review fulfills the DHS commitment to seek public input via the Federal Register on a three-year cycle.

It is important to note that DHS continually evaluates its regulatory program for rules that are candidates for retrospective review. DHS does so through legally mandated retrospective review requirements (e.g., Unified Agenda reviews and reviews under section 610 of the Regulatory Flexibility Act) and through other informal and long-established mechanisms (e.g., use of Advisory Councils, feedback from DHS field personnel, input from internal working groups, and outreach to regulated entities). This Federal Register notice supplements these existing extensive DHS retrospective review efforts.1

II. DHS's Regulatory Responsibility

DHS's mission is to ensure a homeland that is safe, secure, and resilient against terrorism and other hazards. The Department carries out its mission through the Office of the Secretary and 28 components, including the following seven operational components: U.S. Citizenship and Immigration Services, U.S. Coast Guard, U.S. Customs and Border Protection, Federal Emergency Management Agency, U.S. Immigration and Customs Enforcement, U.S. Secret Service, and Transportation Security Administration.

Our mission gives us five main areas of responsibility: (1) Prevent terrorism and enhance security; (2) secure and manage our borders; (3) enforce and administer our immigration laws; (4) safeguard and secure cyberspace; and (5) ensure resilience to disasters. To further these areas, DHS has responsibility for a broad range of regulations. For example, to secure and manage our borders, DHS regulates people and goods entering and exiting the United States. DHS, to combat terrorism, regulates aviation security, high-risk chemical facilities, and

infrastructure protection. DHS also issues regulations to administer immigration and citizenship benefits as well as regulations covering maritime safety and environmental protection. Finally, DHS promulgates a wide range of regulations concerning disaster preparedness, response, and recovery.

III. Request for Input

A. Importance of Public Feedback

A central tenet of the DHS Final Plan is the critical and essential role of public input in driving and focusing DHS retrospective review. Because the impacts and effects of a rule tend to be widely dispersed in society, members of the public—especially the regulated entities of our rulemakings—are likely to have useful information, data, and perspectives on the benefits and burdens of our existing regulations. Given this importance of public input, the primary factor for rule section in DHS retrospective review is public feedback.

B. Maximizing the Value of Public Feedback

This notice contains a list of questions, the answers to which will assist DHS in identifying those regulations that may benefit from DHS retrospective review. DHS encourages public comment on these questions and seeks any other data commenters believe are relevant to DHS's retrospective review efforts. The DHS Final Plan provides instruction on the type of feedback that is most useful to the Department:

DHS will afford significantly greater weight to feedback that identifies specific regulations, includes actionable data, or provides viable alternatives that meet statutory obligations and regulatory objectives. Feedback that simply states that a stakeholder feels strongly that DHS should change a regulation, but does not contain specific information on how the proposed change would impact the costs and benefits of the regulation, is much less useful to DHS. DHS is looking for new information and new economic data to support any proposed changes. (emphasis added)

We highlight a few of those points here, noting that comments that will be most useful to DHS are those that are guided by the principles below. Commenters should consider these principles as they answer and respond to the questions in this notice.

• Commenters should identify, with specificity, the regulation at issue, providing the Code of Federal Regulation (CFR) cite where available.

• Commenters should provide, in as much detail as possible, an explanation why a regulation should be modified,

¹Twice a year, DHS posts a progress report on the DHS Web site; the report provides the status of DHS regulations currently under retrospective review. The most recent progress report was published in July 2013 and is available on the DHS Web site at http://www.dhs.gov/latest-progress.

streamlined, expanded, or repealed, as well as specific suggestions of ways the Department can better achieve its regulatory objectives.

- Commenters should provide specific data that document the costs, burdens, and benefits of existing requirements. Commenters might also address how DHS can best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations and whether there are existing sources of data that DHS can use to evaluate the post-promulgation effects of its regulations over time.
- Particularly where comments relate to a rule's costs or benefits, comments will be most useful if there are data and experience under the rule available to ascertain the rule's actual impact. For that reason, we encourage the public to emphasize those rules that have been in effect for a sufficient amount of time to warrant a fair evaluation.
- Comments that rehash debates over recently issued rules will be less useful.

C. List of Questions for Commenters

The below nonexhaustive list of questions is meant to assist members of the public in the formulation of comments and is not intended to restrict the issues that commenters may address:

- (1) Are there regulations that simply make no sense or have become unnecessary, ineffective, or ill advised and, if so, what are they? Are there regulations that can simply be repealed without impairing the Department's regulatory programs and, if so, what are they?
- (2) Are there regulations that have become outdated and, if so, how can they be modernized to better accomplish their regulatory objectives?
- (3) Are there regulations that are still necessary, but have not operated as well as expected such that a modified, stronger, or slightly different approach is justified?
- (4) Does the Department currently collect information that it does not need or effectively use to achieve regulatory objectives?
- (5) Are there regulations that are unnecessarily complicated or could be streamlined to achieve regulatory objectives in more efficient ways? If so, how can they be streamlined and/or made less complicated?
- (6) Are there regulations that have been overtaken by technological developments? Can new technologies be leveraged to modify, streamline, or do

away with existing regulatory requirements?

- (7) Are there any Departmental regulations that are not tailored to impose the least burden on society, consistent with achieving the regulatory objectives?
- (8) How can the Department best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations? Are there existing sources of data the Department can use to evaluate the post-promulgation effects of regulations over time?
- (9) Are there regulations that are working well that can be expanded or used as a model to fill gaps in other DHS regulatory programs?
- (10) Are there any regulations that create difficulty because of duplication, overlap, or inconsistency of requirements?

The Department notes that this notice is issued solely for information and program planning purposes. Responses to this notice do not bind DHS to any further actions related to the response.

Christina E. McDonald,

Associate General Counsel for Regulatory Affairs.

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