

**SCHEDULED FOR ORAL ARGUMENT ON APRIL 19, 2012
No. 11-5265**

IN THE
**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

**Texas Alliance For Home Care Services
and Dallas Oxygen Corporation**
Plaintiffs-Appellants

v.

Kathleen Sebelius, in her official capacity as Secretary,
U.S. Department of Health and Human Services, and
Marilyn Tavenner, in her official capacity as Acting
Administrator, Centers for Medicare and
Medicaid Services
Defendants-Appellees

*On Appeal from the United States District Court
for the District of Columbia, No. 1:10-cv-747-RCL*

BRIEF FOR THE APPELLANTS

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Certificate as to Parties, Rulings, and Related Cases

(A) Parties and *Amici*

The following entities were parties who appeared before the district court and/or are parties to this appeal. There were, and are, no *amici* or intervenors.

Texas Alliance for Home Care Services ("TAHCS") was a Plaintiff before the district court and is an Appellant in this Court. TAHCS is a trade association incorporated in the State of Texas that represents numerous Medicare suppliers of durable medical equipment, prosthetics, orthotics, and supplies ("DME") in Texas.

Dallas Oxygen Corporation ("DOC") was a Plaintiff before the district court and is an Appellant in this Court. DOC is a member of TAHCS and an accredited and bonded Medicare supplier of DME in Texas.

Kathleen Sebelius was a Defendant, in her official capacity, before the district court, and is an Appellee in this Court. Ms. Sebelius was then, and is now, the Secretary of the United States Department of Health and Human Services.

Marilyn Tavenner was a Defendant, in her official capacity, before the district court, and is named as an Appellee in this Court. At the time the Complaint was filed, Ms. Tavenner was Acting Administrator of the Centers for Medicare & Medicaid Services ("CMS") within HHS. Subsequent to the filing of the Complaint, Donald M. Berwick has occupied the position of Administrator of

CMS. Plaintiffs attempted to replace Ms. Tavenner with Mr. Berwick in their Motion for Leave to File First Amended Complaint. App. ____.

There were no intervenors or *amici* before the district court, and there are currently no intervenors or *amici* before this Court.

Neither TAHCS nor DOC has a parent corporation, and no publicly owned corporation owns 10% or more of the stock of either.

(B) Rulings Under Review

Appellants TAHCS and DOC seek review of the decision of the district court granting a motion by Defendants HHS and CMS to dismiss the case in its entirety. A Memorandum Opinion and Order were issued on September 9, 2011, by Chief Judge Royce C. Lamberth¹ of the United States District Court for the District of Columbia. The opinion and order are in Appellants' Appendix. The opinion has not yet been officially reported, and can be accessed on Westlaw at 2011 WL 4005295 (No. 10-cv-747).

(C) Related Cases

This case on appeal has not previously been before this Court or any other court (except the U.S. District Court from which the appeal is taken). Counsel is not aware of any related cases currently pending in this Court or any other court.

¹ The case was initially assigned to Judge Henry H. Kennedy and was later re-assigned to Chief Judge Lamberth.

A case raising some of the same issues was brought in the United States District Court for the District of Columbia in 2008. The case was dismissed without prejudice on stipulation of both parties on July 25, 2008 after the district court (Judge Urbina) denied Plaintiff's motion for a preliminary injunction on June 30, 2008 on the sole basis of a failure to demonstrate irreparable injury. The opinion in the case was not officially published and can be accessed on Westlaw. *Am. Ass'n for Homecare v. Leavitt*, No. 08-cv-0992, 2008 WL 2580217 (D.D.C. June 30, 2008).

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Rule 26.1 of the Circuit Rules of this Court, Appellants Texas Alliance for Home Care Services and Dallas Oxygen Corporation, through the undersigned counsel of record, hereby submit that neither Appellant corporation has a parent company nor does a publicly-held corporation own 10% or more of its stock.

Appellant Texas Alliance for Home Care Services ("TAHCS") is a corporation incorporated in the State of Texas that represents the Texas durable medical equipment industry as a trade association. Many of its members are accredited and bonded Medicare DME suppliers, serving Medicare beneficiaries in Round 1 rebid and Round 2 competitive bidding areas. Its members include companies that applied to Appellees for approval as contract suppliers of DME pursuant to the applicable Medicare provisions of the Social Security Act, and submitted bids and the financial documentation required by the Appellees, and which Appellees reviewed for the Round 1 rebid, and TAHCS members plan to submit such bids and documentation in Round 2. Many of those members are small providers within the definition promulgated by CMS. TAHCS conducts advocacy on behalf of its members before HHS and CMS, counsels its members on Medicare DME government relations matters and legal compliance, and keeps them informed of developments in the DME industry.

Appellant Dallas Oxygen Corporation ("DOC") is incorporated in Texas and is an accredited and bonded Medicare DME supplier and a member of TAHCS. It supplies more than 3,000 customers in Texas with many types of DME. DOC applied to Appellees for approval as a contract supplier of DME under Medicare, and submitted bids and the financial documentation required by Appellees, which Appellees reviewed for the Round 1 rebid, and DOC plans to submit such bids and documentation in Round 2. DOC is also a small business provider of such equipment under the definition of a small business provider in the Appellees' final rule on DME competitive bidding.

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GLOSSARY

App.	Appendix
CBA	Competitive Bidding Area
CBIC	The Agency's DME Competitive Bidding Implementation Contractor
CMS	Centers for Medicaid & Medicare Services
Compl.	Complaint
DME (or DMEPOS)	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DOC	Dallas Oxygen Corporation
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MTD and MTD Exh.	The agency's Motion to Dismiss, Memorandum in Support, and Exhibit
MLTAC-1, 2, and 3	First, Second, and Third Motions for Leave to Amend Complaint (¶ citations are to attached proposed amended Complaints)
NPRM	Notice of Proposed Rulemaking (Fed. Reg.)
PAOC	Program Advisory and Oversight Committee
RFB	Request for Bids
TAHCS	Texas Alliance for Home Care Services

STATEMENT OF JURISDICTION

The district court had original jurisdiction under 28 U.S.C. § 1331 because this suit arises under the laws of the United States.

This Court has jurisdiction pursuant to 28 U.S.C. § 1291 because this is an appeal from a final decision of a United States district court.

This appeal was timely filed on October 6, 2011.

This appeal is from a final district court order that disposed of all claims on September 9, 2011. The court granted an agency Motion to Dismiss under Fed. R. Civ. P. 12(b)(1) and 12(b)(6) with a Memorandum Opinion¹ and Order. App. a112, a157.

THE ISSUES

1. Preclusion. Preclusion of judicial review requires clear and convincing evidence of Congressional intent to preclude. The DME statute precludes any administrative or judicial review of "the awarding of contracts" or "the bidding structure." Neither that language, nor other indicia of legislative intent, show clear and convincing evidence of intent to preclude judicial review of basic systemic issues concerning adequacy of rulemaking notice and comment and agency compliance with the statutory mandate to specify supplier financial standards.

¹ *Texas Alliance for Home Care Services*, No.10-cv-747, 2011 WL 4005295 (D.D.C., Sept. 9, 2011). App. a112. There was no oral argument.

2. Standing. Standing is "self-evident" where the plaintiffs are the object of the regulatory action at issue. The Plaintiffs/suppliers must meet "financial standards specified" by the agency, "taking into account the needs of small providers." They are thus entities directly subject to the rulemaking at issue. Standing is therefore self-evident from the administrative record and other facts set out in the Complaint, as well as from facts alleged in the three motions for leave to amend the Complaint.

3. Notice and comment. The agency NPRM failed utterly to propose any specific financial standards on which the suppliers could comment. The NPRM proposed only to require certain types of company-specific financial documentation and data and simply invited comment on the general issue of financial standards. The NPRM also stated that the agency was still developing a financial standards "methodology," but did not propose any such methodology

4. Specification of standards. The statute requires the Secretary to specify financial standards. The agency's interim final rule and two final rules do not contain anything that can be regarded as specification of financial "standards." They contain only requirements for submission of financial documentation, without specifying what standards would be used to evaluate that documentation to determine whether a supplier is qualified to bid. The agency has indicated a

number of times that it is withholding the methodology for "scoring" the information, and a scoring "cutoff" or "threshold."

These are the principal issues. Subsidiary and related issues -- such as the adequacy of the factual allegations in the Complaint, whether the district court should have granted the motions for leave to amend the Complaint, consideration of the needs of small businesses, asserted Congressional ratification, and lack of FOIA disclosure of the supposed standards -- are assumed to be encompassed by the four main issues and will be touched on briefly.

STATEMENT OF FACTS²

This case was brought because the Plaintiffs (TAHCS members and DOC), suppliers of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS," hereafter "DME") under Medicare, mainly small businesses servicing areas throughout Texas, including Round 1 rebid and Round 2 competitive bidding areas ("CBA"s), have no idea what "financial standards," if any, are being applied by the agency to determine whether they and other suppliers are qualified to bid for Medicare DME contracts. Nor have they seen the reasoning supporting any such standards, and have never had an opportunity to comment on proposed financial standards. Their financial documentation was about to be

² All relevant portions of the statutes, rulemaking notices, and C.F.R. references in this section are set out in the attached Statutory and Regulatory Addendum.

evaluated by the agency for the Round 1 rebid when the Complaint was filed in May 2010, and they are now preparing to submit financial documentation for the vastly larger Round 2 of competitive bidding.

In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") Congress extensively amended the Medicare provisions of the Social Security Act. Pub. L. No. 108-173, Dec. 8, 2003. Section 302 of Title III of the MMA addressed changes to the DME program. Those changes included, in the main, replacing the previous fixed-fee reimbursement schedule with a system for establishing fees through competitive bidding in major metropolitan areas in several implementation rounds, and requiring HHS to specify quality and financial standards that all DME suppliers must meet.

The MMA provided that a DME supplier cannot qualify to bid unless it "meets applicable financial standards specified by the Secretary, taking into account the needs of small providers." 42 U.S.C. § 1395w-3(b)(2)(A)(ii).³ It also contained the provisions precluding administrative or judicial review of seven specific types of agency implementing decisions, including "the awarding of contracts" and "the bidding structure." 42 U.S.C. § 1395w-3(b)(11)(B) and (F).

³ Title 42 of the United States Code has not been enacted into positive law pursuant to 2 U.S.C. § 285b, but the DME provisions, as amended, appear to be accurately set out in the GPO FDsys version of the Code in the Addendum. The DME portions of the Public Laws are also set out in the Addendum.

To implement the MMA, on May 1, 2006 the agency issued a notice of proposed rulemaking ("NPRM") that purported to propose "financial standards" for DME suppliers. 71 Fed. Reg. 25654. However, the substance of the proposal stated only that "suppliers must meet the applicable financial standards specified in the request for bids." 71 Fed. Reg. at 25700 3d col., sec. 414.414(d). The request for bids ("RFB") was not a part of the NPRM, and was not even indicated to be otherwise available at that time. When the RFB was later made available on the Internet (apparently only in the form of RFB Instructions on May 15, 2007, App. a158, a160), it provided only that suppliers applying to bid would have to submit certain financial documents and information, and did not indicate what standards would be applied to those documents and information. App. a160. The preamble to the NPRM indicated that the agency was still working to "develop our methodology for financial standards," but gave no hint of the methodology. 71 Fed. Reg. at 25675 2d col. The NPRM simply stated that the agency would "welcome comments on the financial standards, in particular the most appropriate documents that will support these standards." *Id.*

On April 10, 2007, the agency issued a final rule which purported to specify financial standards for DME suppliers. 72 Fed. Reg. 17992. The substantive final rule simply stated, under the heading of "Financial standards," that "[e]ach supplier must submit **along with its bid** the applicable financial documentation specified in

the request for bids." 72 Fed. Reg. 18088 2d col., sec. 414.414(d) (emphasis added). The preamble did not make any mention of the "methodology" that the agency had stated in the NPRM it was developing. The preamble also discussed comments submitted on the financial standards portion of the NPRM. Among those were comments, first, that the agency should "publish the criteria it will use to assess supplier's [sic] financial stability and how it will rank suppliers based on these criteria" (72 Fed. Reg. at 18037 3d col.); and, second, that the agency should "define a set ratio, for example, asset ratio [sic] should be [sic] not be higher than (X percent) and the asset to liability ratio should be no lower than (X percent)." 72 Fed. Reg. at 18038 1st col. With regard to the first comment, the agency stated only that it would use the financial information required to be submitted "to assess a supplier's financial soundness" 72 Fed. Reg. at 18037 3d col. With regard to the second comment, the agency responded, tellingly, that it would use appropriate financial ratios to evaluate suppliers, and "[i]f suppliers **do not meet certain ratios**, they could be disqualified from the competition." 72 Fed. Reg. at 18038 1st col. (emphasis added). Those "certain ratios" that suppliers must meet have never been disclosed, through rulemaking or otherwise.

On July 15, 2008, just after Round 1 of the competitive bidding had been completed by the awarding of supplier contracts, Congress, responding to numerous supplier complaints concerning technical glitches and delays,

complexity of the new program, and agency and CBIC handling of required financial documents, amended the MMA DME provisions in sec. 154 of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"). MIPPA canceled all Round 1 supplier contracts recently awarded, delayed Round 1 for approximately two years, and added requirements to provide suppliers with a structured opportunity to remedy any apparent deficiencies in the financial documentation they had submitted. MIPPA did not amend the MMA provisions regarding DME financial standards to be specified by HHS or the relevant judicial review preclusion provisions.

MIPPA's new schedule for bidding required re-bidding during 2009 in the 10 Round 1 CBAs, which included the Dallas-Fort Worth-Arlington, TX metro area, and Round 2 bidding during 2011 in 91 additional metropolitan CBAs, and other areas thereafter. 42 U.S.C. § 1395w-3(a)(1)(B) and (D).

In order to implement MIPPA, the agency issued an interim final rule on January 16, 2009. 74 Fed. Reg. 2873. The interim final rule contained a substantive rule on "Financial standards" that was substantially the same as in the final rule of April 2007, except that, as a result of the MIPPA amendments, it now referred to the required financial documents as "covered documents." 74 Fed. Reg. at 2880-81, 42 C.F.R. § 414.414(d) (2011). The preamble did not specifically discuss the "financial standards" rule, except to the extent that it explained that that

the agency had decided it would be sufficient to require only one year (rather than three years) of financial documentation because, it stated, "We believe that we can determine whether a supplier **demonstrates financial soundness** by reviewing one year of documentation." 74 Fed. Reg. at 2876 (emphasis added).

Bidding must be re-competed every three years. 42 U.S.C. § 1395w-(b)(3)(B).

The Round 1 rebid was delayed and was mainly conducted during 2010. At the time the Complaint was filed in this case, May 10, 2010, prospective suppliers were undergoing accreditation⁴ and were assembling documentation for submission, but no contracts had been awarded. Contract awards, as well as rejections, for Round 1 were announced on November 3, 2010 and went into effect on Jan. 1, 2011. App. a187.

On November 10, 2011, the agency issued a final rule to take the place of the interim final rule. 76 Fed. Reg. 70228. The regulatory provision for "Financial standards" was the same as in the interim final rule, and there was no discussion of the subject in the preamble.

But the rulemaking notices do not tell the whole story -- or even much of the story -- regarding the agency's treatment of the statutory mandate to specify

⁴ Accreditation is primarily the process of ensuring, through onsite visits and otherwise, that prospective suppliers meet the DME quality standards issued under 1395w-3(b)(2)(A)(i).

supplier financial standards. On several occasions since the interim final rule in April 2007 and the awarding of Round 1 rebid contracts in November 2010, the agency has indicated that it, and its competitive bidding implementation contractor ("CBIC"), Palmetto GBA, are employing some sort of "financial standards" that it will not disclose and were never proposed. As noted above, the 2007 final rule preamble stated that supplier's could be disqualified from the program if they "do not meet certain ratios" At the 2008 Congressional subcommittee hearing referenced by the district court, the agency (Mr. Weems testifying) admitted that the agency had not told suppliers how it was using financial ratios to judge "financial viability," and had not told them how they would be "scored." App.

a150. And the RFB (request for bids) Instructions state:

CMS determines a supplier's financial viability based on financial ratios calculated from the bidder's submitted financial information. The financial ratios can be found on the CBIC website. All bidders must meet CMS' **established financial thresholds** to be considered for a contract. [Emphasis added.]

App. 161. Nowhere in their rulemaking (or elsewhere) has the agency disclosed such "established financial thresholds." Also, the agency's Motion to Dismiss ("MTD") indicated that it was justified in withholding the financial standards due to its concerns that prospective bidders might fraudulently manipulate their data submissions to achieve compliance. App. a21-a24. Moreover, when Round 1 rebid contracts were awarded in November 2010, the agency's CBIC sent to bidders

whose bids had been rejected a form indicating the reason(s) for rejection. App. a187-a189. That form indicated, in the fourth column, that one of the reasons for rejection could be that "Financial Score Does not Meet the Financial Requirements," and a footnote to that column heading indicated that a "financial score" would have been "calculated" by the CBIC if the financial documentation submitted had been found to be in order. App. a189.⁵ In April 2011, Texas Medical, Inc., which had received a Round 1 rebid rejection form, submitted a FOIA request to the agency for records pertaining to how they (or the CBIC) calculated the "financial score" indicated on the forms App. a190. To date, Texas Medical has not received a response from the agency, despite the agency having received and acknowledged the FOIA request more than seven months ago. App. a191-a193.

The current Round 2 timeline contains target dates for submission of bids and "covered [financial] documents" during the period from January 30, 2012 until March 30, 2012; beginning of the process of selecting suppliers to be offered contracts in Spring 2012; announcement of contract awards in Spring 2013; and an effective date for Round 2 contracts of July 1, 2013. App. a194.

⁵ The third column of the form was titled "Financial Documents Do Not Meet Requirements," indicating that that the "financial score" is something separate from the required financial documentation. In addition, the "financial score" is presumably different from a "credit score," which had to be calculated by an outside credit rating organization and was required to be submitted as financial documentation .

Round 2 includes six CBAs in Texas that were not in the Round 1 rebid and in which the Plaintiff suppliers plan to bid. The individual Medicare DME beneficiary proposed to be added as a plaintiff in MLTAC-3 resides in a New Jersey Round 2 CBA. App. a195-a196.

SUMMARY OF THE ARGUMENT

Financial documents are not financial "standards." The agency's proposed and final rules only address requirements for submission of certain company-specific financial documents, from which the agency will extract certain types of company-specific financial ratios. Although the agency has considerable discretion and flexibility to craft the financial "standards," they must be measures, models, or criteria that can be applied on a uniform, objective basis, not just company-specific data from which the agency can make *ad hoc*, arbitrary decisions regarding financial soundness. The agency's rulemakings are plainly contrary to the Congressional mandate to specify financial standards, taking into account the needs of small providers.

Further, the agency has never proposed financial "standards" for meaningful public comment, and has not promulgated any financial "standards" via rulemaking. A valid rulemaking proposal requires an actual proposal and discussion of alternatives and supporting reasoning, and the final rule must be a "logical outgrowth" of the proposal and must state the agency's reasoning for

adopting the final rule. The "general principles" endorsed by the district court as financial standards -- apparently "overall financial soundness" or financial "viability" or "stability" -- were never proposed as standards in the rulemaking, and cannot be considered "standards" as a matter of law because they simply restate the obvious purpose of the statutory mandate, providing no additional guidance, and allow for *ad hoc* and arbitrary decisionmaking. And such general principles, stated only in the preamble of the final rule, cannot be considered a "logical outgrowth" of a proposed rule because there was nothing for them to grow out of -- no proposal of them as standards in the NPRM.

Moreover, the agency has indicated at various times and in various fora (the preamble to the 2007 final rule, in a Congressional hearing, in its Motion to Dismiss, in its RFB Instructions, through its CBIC in the Round 1 rebid rejection forms, and in its failure to respond to the FOIA request for documents showing how it calculates the "financial score" referred to in the rejection forms), that it is employing some sort of financial standards that it has intentionally not disclosed in its rulemaking. The agency has thereby effectively conceded that what is in its rulemaking is not sufficient to satisfy the statutory mandate and requirements for adequate notice and comment.

The district court held that the fundamental procedural requirements of adequate notice and comment and compliance with the statutory mandate to

specify financial standards at issue in this case are not subject to judicial review because the statute precludes judicial review of the "awarding of contracts" and "the bidding structure," among a list of other very specific preclusions. As the district court correctly stated, judicial review can be precluded only when Congressional intent to preclude is clear and convincing. But the district court erred in holding that judicial review of the adequacy of notice and comment and compliance with the statutory mandate to specify financial standards was precluded despite the lack of any mention in the statute or its legislative history of preclusion of agency specification of financial standards, or even of rulemaking decisions. Instead, the district court based its holding only on strained inferences derived from the textual structure of the statute and some judicial opinions lacking relevance or containing *dicta*. The district court also erred in reversing the burden to show preclusion (at least on the "bidding structure" preclusion provision) by finding that the suppliers had not provided evidence of Congressional intent not to preclude. Furthermore, the district court erred in not recognizing that intent to preclude is even more difficult to infer when such fundamental statutory requirements as adequate notice and opportunity to comment and compliance with a statutory mandate are at issue.

With regard to Article III standing, the district court's finding that the Complaint, or proposed amendments to the Complaint, failed to demonstrate

standing is contrary to this Circuit's case law holding that entities directly regulated by a challenged regulation, as indicated by the administrative record, are considered to have "self-evident" standing. And even if standing were not "self-evident" from the administrative record facts set out in the Complaint, the three motions for leave to amend the Complaint supplied more than adequate bases for standing and should have been granted.

The district court opinion is fatally flawed in all of its essential holdings and must be reversed. This Court should vacate the defective rulemaking proceedings and remand to the agency to undertake legally compliant rulemaking for supplier financial standards.

GENERAL STANDARD OF REVIEW

This Court reviews *de novo* a district court grant of a motion to dismiss on either 12(b)(1) or 12(b)(6) grounds. In doing so, the Court assumes all factual allegations in the Complaint to be true, and construes the Complaint liberally to support all reasonable inferences from the alleged facts that are favorable to the Plaintiffs. LaRoque v. Holder, 650 F.3d 777, 785 (D.C. Cir. 2011) (citations omitted).⁶

⁶ If the Court determines that any motion for leave to amend the Complaint should have been granted, it would apply the same standard of review to the amended Complaint.

Additional aspects of the standard of review applicable to individual issues are explained below at the beginning of the argument on each such issue.

ARGUMENT

Although the substantive heart of this case is the lack of adequate rulemaking notice and opportunity to comment and failure to comply with the statutory mandate to specify DME supplier financial standards, we necessarily begin with those issues concerning the court's subject matter jurisdiction -- preclusion and standing -- as did the district court.

I. The statutory provisions precluding any administrative or judicial review of the "awarding of contracts" or the "bidding structure" (42 U.S.C. § 1395w-3(b)(11)) do not preclude judicial review for the types of systemic statutory mandate issues in this case.

Although the initial burden is on the plaintiff to establish subject-matter jurisdiction, when the agency asserts that a statutory provision precludes judicial review the burden shifts and the agency faces the "strong presumption" in favor of judicial review and has the "heavy burden" of demonstrating by "clear and convincing evidence" that Congress intended to preclude judicial review.

Gutierrez v. Lamagno, 515 U.S. 417, 424 (1995); McNary v. Haitian Refugee Ctr., Inc., 498 U.S. 479, 496, 498 (1991); Bowen v. Michigan Academy of Family

Physicians, 476 U.S. 667, 670, 671-72 (1986)⁷; Safe Extensions, Inc. v. FAA, 509 F.3d 593, 601 (D.C. Cir. 2007). Evidence of Congressional intent to preclude can be provided by the plain language of the statute or by other clear indicia of legislative intent gathered from the legislative history or the statutory scheme. Block v. Community Nutrition Inst., 467 U.S. 340, 349 (1984). But in any event, the evidence of Congressional intent must be "clear and convincing."

The strong presumption favoring judicial review is particularly strong when the issue is agency compliance with a statutory mandate, as opposed to a fact-specific determination that has limited significance as precedent. The presumption applies particularly in Medicare cases where, as here, the lack of a channel for administrative review followed by judicial review would mean no judicial review at all. Michigan Academy, 476 U.S. at 681 ("We ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command."); Action Alliance of Senior Citizens v. Leavitt, 483 F.3d 852, 859 (D.C. Cir. 2007).

⁷ The district court's statement that Michigan Academy (*i.e.*, "Bowen"), has been "expressly overruled" (Slip Op. *23 n.10) is inaccurate. Michigan Academy was superseded by statute when the Medicare provisions involved were amended, but its reasoning, as referenced above, is still regarded as valid. Gutierrez, 515 U.S. at 424; McNary, 498 U.S. at 497-98.

In a case like this where Congress has delineated specific areas of agency decisionmaking for preclusion, and preclusion is not readily apparent from the plain language of the statute, it is significant that Congress, presumably aware of the strong presumption against preclusion, could well have used broad language if it intended broad preclusion. McNary, 498 U.S. at 494; Lindahl v. OPM, 470 U.S. 768, 779-80 & n. 13 (1985) (giving specific examples of use of such broad preclusion language); Amgen, Inc. v. Smith, 357 F.3d 103, 111-12, 114 (D.C. Cir. 2004) ("review of certain system-wide determinations by the Secretary has been held to be available notwithstanding an express preclusion on [sic] review of individual determinations ") (internal citation omitted). The list of DME preclusions is very specific and detailed, but it makes no mention of preclusion of financial standards or a number of other program aspects such as specification of quality standards or access of individuals to a choice of multiple suppliers. The statutory construction canon of *inclusio unius est exclusio alterius* plainly applies here.⁸

Finally, in the present case, awarding DME contracts without having specified financial standards for DME suppliers could well be considered agency action beyond its authority and *ultra vires*. see Amgen, 357 F.3d 103, 111-12, 114

⁸ The district court's rejection of the *inclusio unius* doctrine (App. a29 n. 8) is mystifying, and it is apparently based on the *a priori* conclusion that "bidding structure" "necessarily encompasses 'financial standards.'"

(D.C. Cir. 2004) (presumption in favor of judicial review is "particularly strong" in cases where the agency action is alleged to be in excess of delegated authority -- *i.e.*, *ultra vires* -- and "the wording of a preclusion clause is less than absolute"); Dart v. United States, 848 F.2d 217, 221 (D.C. Cir. 1988).

- A. "Awarding of contracts" plainly refers to actual contracting with individual entities, and to preclusion of review of decisions involved in such specific awards. It does not refer to broad claims regarding defective rulemaking process or failure to comply with statutory mandates that are not involved in a specific contract award decision. There is no clear and convincing evidence that Congress intended otherwise.**

A "contract" is an agreement between specific parties, and preclusion of review of the "awarding of contracts" plainly refers to review of agency determinations regarding individual contracts, not to preclusion of every systemic issue somehow related to the awarding of contracts. If the statutory wording is not enough, relevant legislative history confirms that this preclusion language was intended to apply only to specific contract awards. The Senate conference report on the MMA confirms that this particular preclusion wording was intended to apply to "contract awards," thereby plainly indicating individual awards. H.R. Rep. No. 108-391, 108th Cong., 1st Sess. (2003) (Conf. Rep.) at 596 (explaining judicial preclusion provisions that use the same wording -- "awarding of contracts" -- in the provisions of the MMA for competitive acquisition of drugs and biologicals, 42 U.S.C. §§ 1395w-3b and 1395w-3b(g)). In view of the wording of

the provision and this evidence of legislative intent, it is not possible to conclude that Congress intended this very specific provision to bar judicial review of systemic procedural issues of adequate notice and opportunity to comment and compliance with the statutory mandate to specify supplier financial standards.

This is particularly true because at the time the Complaint was filed there had been no "awarding of contracts" in the Round 1 rebid, and there currently has been no awarding of contracts in Round 2.

However, the district court, rather than focusing on the plain language of the provision and evidence of Congressional intent, decided that the provision precluded judicial review of **all** issues involved in implementation of the competitive bidding "program." App. a156 (and a129, a131, a132, and a134 with regard to "bidding structure" as bidding "program"). In place of the plain language and evidence of legislative intent, the district court relied on several court opinions that it believed established that courts should not distinguish in this case between standards of eligibility (the requirement that suppliers meet the financial standards specified by the agency) and the rulemaking process of specifying such standards on the one hand, and the actual awarding (or not awarding) of a specific contract on the other, as well as the textual arrangement of the statutory provisions. In fact, the district court did not even state a conclusion that it had found clear and

convincing evidence of Congressional intent to use the "awarding of contracts" language to preclude broad, systemic issues.

The cases relied on by the district court to find preclusion were: Corel Corp. v. United States, 165 F. Supp. 2d 12, 28-29 (D.D.C. 2001); Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 13-14 (2000); All Fla. Network Corp. v. United States, 82 Fed. Cl. 468, 473 (2008); and Atl. Urological Assoc., P.A. v. Leavitt, 549 F. Supp. 2d 20, 30 (D.D.C. 2008). App. a127-a128. Each of these cases is distinguished below in the order the district court referenced them. Not one of these decisions supports the district court's position on preclusion.

Corel Corp. concerned a federal procurement bid protest, not a DME contract award. Corel, protesting a specific procurement decision, argued that the decision was arbitrary and capricious. The government argued that the bid protest was barred by a specific statutory procurement provision. But the court did not decide the preclusion issue, stating that it did not need to resolve the issue because even if the challenged procurement decision were reviewable, it was not arbitrary and capricious. 165 F.Supp. at 29.

The Supreme Court's decision in Illinois Council is not pertinent, and actually even supports the suppliers' position in this case. In Illinois Council, the Court held that where the Medicare statute provides an avenue for administrative review of a decision, a party challenging the decision must first go through that

administrative process to raise a systemic federal question issue in order to seek judicial review of that issue. Of particular significance is the Court's position that the Michigan Academy strong presumption against preclusion applies if there would be "no review at all" if preclusion were found. 429 U.S. at 19. *And see* Action Alliance of Senior Citizens v. Leavitt, 483 F.3d 852, 859 (D.C. Cir. 2007) (recognizing that Supreme Court position). The language the district court quotes from Illinois Council was directed to the Court's determination that all types of challenges -- whether factual, legal or "collateral" in nature -- relating to a specific reimbursement decision must first be channeled through the administrative appeal process before being presented to the courts. In the present case, there is no channel for administrative review followed by judicial review, and a finding of preclusion would result in "no review at all" -- the very thing the Supreme Court sought to prevent in Michigan Academy. The statutory preclusion provisions in this case expressly foreclose all administrative and judicial review, stating at the beginning, that there will be "no administrative or judicial review ... under section 1395ff ... section 1395oo ... **or otherwise**" of the specified types of determinations. (Emphasis added.) 42 U.S.C. 1395w-3(b)(11).

All Fla. Network concerned a specific CMS contract award decision (not to award a contract) because a number of the required financial documents had not been submitted. The court held that the supplier was challenging a **specific**

decision not to award a contract, and that Congress intended to preclude judicial review of "specific decisions" regarding contract awards. 82 Fed. Cl. at 474. The court stated:

Plaintiff does not here challenge the terms of the RFB nor take issue with the substance of the bidding qualifications established by CMS. Instead, Plaintiff challenges CMS' determination that **it** did not meet those qualifications. Plaintiff is therefore directly challenging a CMS decision regarding "the awarding of contracts." [Emphasis added]

82 Fed. Cl. at 473. In the present case, the suppliers are not challenging any specific decision to award or not award a contract.

Finally, Atl. Urological Assoc. involved a situation like that in Illinois Council, and the court found that the plaintiffs could pursue their systemic legal claims (*e.g.*, failure to follow APA notice and comment procedures) by first channeling them through the administrative review process, and therefore such channeling would not result in "no review at all." 549 F. Supp. 2d at 32. Here, the Plaintiffs do not have a channel for administrative review. Thus, preclusion in the present case would result in no review at all.

In concluding that the present suit was precluded both by the language "awarding of contracts" and the "bidding structure," the district court also relied on its perceptions regarding the statutory scheme. But the court's reasoning here is distinctly opaque and shifts the burden to the plaintiffs to show non-preclusion, stating that "plaintiffs point to nothing in the record or legislative history ... to

suggest that Congress did not intend to bar judicial review of the entirety of the Secretary's development of the DME Bidding Program." App. a134. The court's analysis appears to be in the nature of an *ipse dixit* that Congress must have intended to insulate all aspects of the DME program from judicial review and that "bidding structure" (discussed below) necessarily encompasses "financial standards."⁹ The court drew support from Cardiosom, L.L.C. v. United States, 656 F.3d 1322 (Fed. Cir. 2011), and Carolina Med. Sales, Inc. v. Leavitt, 559 F. Supp. 2d 69 (D.D.C. 2008). Neither of those cases support the court's position on preclusion.

In Cardiosom, the plaintiff sued for breach of contract and uncompensated taking after MIPPA cancelled its original DME Round 1 contracts in 2008. The issue was whether a provision in MIPPA disclaiming a private right of action for termination of such contracts reversed the Tucker Act waiver of sovereign immunity for contract actions against the government. The court discerned at least three plausible interpretations of the alleged preclusion language that would be consistent with maintaining a Tucker Act remedy. Because the language the government relied on was therefore ambiguous (and not "clear and unequivocal"),

⁹ See, e.g., App. a129 n. 8 ("financial determinations ... are part of the 'bidding structure'" and "bidding structure necessarily encompasses 'financial standards'." See also App. a132 ("The Secretary's choice of appropriate financial standards to apply in the DME Bidding Process" is a Medicare "management decision" that Congress intended to preclude -- providing no evidence of legislative intent to support that statement).

the court found no preclusion. The district court's reliance on this case is puzzling, since in the present case there are also clearly plausible interpretations of "awarding of contracts" and "bidding structure" (discussed below) other than those found by the district court that would not preclude the claims in this case.

In Carolina Med. Sales, at issue was interpretation of a DME preclusion provision not at issue in this case, paragraph (E), which precludes review of "the selection of items and services for competitive acquisition under subsection (a)(2) of this section" The court determined that plaintiffs' APA challenge (for abuse of discretion and lack of notice and comment) to the Secretary's decision to select mail-order diabetic supplies and not storefront-sold diabetic supplies for competitive acquisition was actually "a direct attack on the Secretary's selection of items and services" and therefore precluded. 559 F. Supp. 2d at 79. In so concluding, the court noted that the Supreme Court's decision in McNary distinguished between a "collateral attack on practices and policies used in processing an application" and "a direct challenge to a determination respecting an application." *Id.*¹⁰ Here, the Plaintiffs' APA challenge is a collateral attack and therefore not precluded.

¹⁰ Although the outcome in Carolina Medical appears supported, it also appears that the court erred in determining the plaintiffs have the full burden of supporting subject matter jurisdiction when preclusion is an issue. At 74-74. The court made no reference to the burden of defendants to overcome the strong presumption in

B. "Bidding structure" plainly refers only to bidding and how it is conducted. It does not encompass the statutory mandate to specify financial standards that suppliers must meet in order to qualify to submit bids. The regulations concerning bidding are distinct from those concerning submission of financial documentation.

The DME statutory provisions define a "bid" as "an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item of service." 42 U.S.C. § 1395w-3(6)(B). A "bid" does not encompass submission of "covered [financial] documents." "Bidding structure" is not defined in the statute or regulations, but it can very plausibly be construed to mean how such bid price offers must be submitted and how the agency will evaluate them, as distinct from whether a particular bidder is financially qualified to submit a bid at the outset by meeting the "financial standards" that the agency was required to specify.

The district court focused on the term "structure," rather than "bidding," and determined that financial standards were part of the structure of the overall bidding "Program" and therefore part of the bidding structure. App. a129. But "bidding structure" indicates that the parts of the structure must be part of the bidding part of the program, while the requirement to specify financial standards is part of the "Program requirements" and the "general" "Conditions for awarding contracts."

favor of judicial review by demonstrating legislative intent to preclude by clear and convincing evidence.

The preclusion is for the "bidding structure," not the "program" structure.

Financial standards, especially as defined by the agency in the form of documentation, are not bids. The bidding structure determines how the competitive bidding is conducted and evaluated in order to determine, based on the bids, who will get a contract. Even if a supplier is financially qualified, that has nothing to do with whether its bid will be acceptable and accepted under the "bidding structure" so that it will receive a contract.

The plausible conclusion that "bidding structure" does not include financial standards is supported by the delineation of procedures for submitting and evaluating bids in the DME regulations separately from the purported financial standards. Under the statute and the regulations, the "bidding structure" is a competitive bidding structure, and how the competition proceeds and is resolved is set out in the DME regulations. Those regulations set forth requirements for submitting bids (42 C.F.R. § 414.412) and a detailed, structured process for how bids will be evaluated to determine competitive bid payment amounts and winning bids. 42 C.F.R §§ 414.414(e) and 414.416. That bid evaluation and payment determination process, which requires submission of "composite bids" and determination of a "median," "pivotal bid" and "single payment amount" that a bidder must be at or below to receive a contract, is separate from the purported "financial standards" in 414.414(d). As the "Financial standards" section

(414.414(d)) states, each supplier must submit the required "covered [financial] documents" "**along with its bid.**" (Emphasis added.)

The bid rejection forms for the Round 1 rebid (App. a189) also distinguish between rejection of a bid because "Bid Amount Above Winning Range" in column one, and the rejection reasons in the other columns pertaining to financial "covered documents" and compliance with "financial standards."

There is no legislative history concerning the Congressional intent behind the preclusion of review of the "bidding structure," nor of the intent behind the requirement to specify financial standards. The only case to consider the meaning of the "bidding structure" preclusion is Sharp Healthcare v. Leavitt, 555 F. Supp. 2d 1121 (S.D. Cal. 2008), which was dismissed by the district court largely because the opinion had been vacated after settlement -- which is not an acceptable reason for disregard of the opinion in this Circuit.¹¹ In Sharp Healthcare, the plaintiffs argued that the agency had violated the APA by requiring them to participate in the bidding process when a provision of the DME statute gave them an express exemption. The agency argued that the requirements for **who** must

¹¹ This Circuit strongly disfavors *vacatur* of an opinion on the basis of a settlement between the parties, especially when it appears that the losing party might have been motivated to dispose of an unfavorable opinion. In re United States, 927 F.2d 626, 627-28 (D.C. Cir. 1991). Such was the case here, where the government settled *Sharp Healthcare* and then moved to vacate the opinion while district court briefing was under way in the present case. *And see* Amaefule v. Exxonmobil Oil Corp., 630 F. Supp. 2d 42, 43-44 (D.D.C. 2009).

submit bids were part of the "bidding structure" and therefore judicial review was precluded. The court disagreed, stating:

“[B]idding structure” may reasonably be interpreted as encompassing only the Secretary's establishment of the procedures or process that bidders must follow. In short, the term is ambiguous, at best, regarding whether it provides the Secretary with unchecked discretion to determine who must submit bids. In light of this ambiguity, the Court finds that the Secretary has not provided “clear and convincing evidence” that Congress intended to preclude judicial review of his interpretation of the face-to-face exception.

555 F. Supp. 2d at 1124-25. In addition, the court found that the government's position on disregard of the provision exempting certain suppliers from bidding was contrary to the principle expressed in Michigan Academy, 476 U.S. at 681, that “Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command.” 555 F. Supp. 2d at 1125. That principle applies to the statutory command to specify financial standards, and to do so following adequate notice and comment procedures.

II. The suppliers' standing is "self-evident" from the administrative record and facts alleged in the Complaint because they are directly subject to the statutory requirement that they must meet financial standards specified by the agency. The three motions for leave to amend that were denied by the district court would have reinforced the standing allegations self-evident from the Complaint.

Article III standing requires that, at the pleading stage, plaintiffs allege sufficient facts to establish that they face an imminent threat of injury, that there is

a causal connection between the injury and the alleged illegal agency action, and that the court can likely redress that threatened injury. Nat'l Ass'n of Homebuilders v. U.S. Army Corps of Engineers, 663 F.3d 470, 473 (D.C. Cir. 2011). "At the pleading stage, 'general factual allegation of injury resulting from the defendant's conduct may suffice,' and the court 'presumes that general allegations embrace the specific facts that are necessary to support the claim.'" Sierra Club v. EPA, 292 F.3d 895, 898-99 (D.C. Cir. 2002) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 561(1992)).

In the case of an alleged failure by the agency to follow required procedures, the Plaintiffs must show that due to that failure they face a distinct risk of imminent harm to a concrete, particularized interest, that the risk of harm is connected to the procedural defect, and that the defect and risk can be redressed by the court. The plaintiffs must show that the government violated procedural rights "designed to protect their threatened concrete interest," and that "the violation resulted in injury to their concrete, particularized interest." Ctr. for Law and Educ. v. U.S. Dept. of Educ., 396 F3d 1152, 1157 (D.C. Cir. 2005). A showing of actual harm is not necessary; imminent harm will suffice. Amer. Chemistry Council v. DOT, 468 F.3d 810, 820 (D.C. Cir. 2006). "[A] plaintiff must show that 'the procedures in question are *designed* to protect some threatened concrete interest of *his* that is the ultimate basis of his standing.'" *Id.* (quoting Lujan v. Defenders of

Wildlife, with original emphasis). A plaintiff alleging a procedural defect must show that omission of the procedure in question will cause "a distinct risk to a particularized interest." Wyo. Outdoor Council v. U.S. Forest Serv., 165 F.3d 43, 51 (D.C. Cir. 1999). Put another way, a plaintiff alleging a procedural violation must show "a causal connection between the government action that supposedly required the disregarded procedure and some reasonably increased risk of injury to its particularized interest." Fla. Audubon Soc'y v. Bentsen, 94 F.3d 658, 664 (D.C. Cir. 1996 (en banc)).

Standing is usually self-evident from the administrative record in a case in which the plaintiffs are subject to the regulation at issue. As stated in Sierra Club, 292 F.3d at 899-900:

In many if not most cases the petitioner's standing to seek review of administrative action is self evident; no evidence outside the administrative record is necessary for the court to be sure of it. In particular, if the complainant is "an object of the action (or forgone action) at issue" - as is the case usually in review of a rulemaking ... - there should be "little question that the [agency] action or inaction has caused him injury, and that judgment preventing or requiring the action will redress it." [Quoting Lujan v. Defenders of Wildlife, 504 U.S. at 461-62.]¹²

A concrete and particularized threatened harm is necessarily speculative to some degree in the case of an alleged procedural defect, such as lack of adequate

¹² And see Cir. Rule 28(7) (in direct administrative appeals, the brief must state arguments and evidence supporting standing only if "petitioner's standing is not apparent from the administrative record," citing Sierra Club, 292 F.3d at 900-01).

notice and opportunity as alleged in this case. But, as stated in Sugar Cane Growers Coop. of Fla. v. Veneman, 289 F.3d 89, 94-95 (D.C. Cir. 2002):

A plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show the procedural step was connected to the substantive result. ... If a party claiming the deprivation of a right to notice-and-comment rulemaking under the APA had to show that its comment would have altered the agency's rule, section 553 would be a dead letter.

In the present case, the Complaint alleges facts, based on the statute and the administrative record (principally the rulemaking notices), that make Article III standing "self-evident." App. a5-a17. It alleges that TAHCS represents Medicare suppliers who are engaged in the Round I rebid competitive bidding process, as is DOC (who is also a member of TAHCS), that they therefore must be found by the agency to meet the financial standards required to be specified by the Secretary under the statute, that the agency has not provided adequate notice and comment for such standards, has not specified such standards, and therefore the agency appears to be qualifying suppliers financially on an *ad hoc* and arbitrary basis. It is self-evident therefore that the plaintiff suppliers face the distinct risk to their Medicare DME business that they will not be found to meet the standards and will lose the opportunity to compete for contracts. Compl. ¶¶ 1, 7, 10, 14, 16, 18, 23, 26, 28, 33, 41, *id.* The plaintiff suppliers' standing could not be more self-evident, nor the "case or controversy" any clearer. If the suppliers cannot challenge those

alleged procedural and substantive deficiencies, there is no other entity that could, and the agency would be free to ignore with impunity Congressional mandates for adequate notice and comment and specification of financial standards.

In case this risk of being disqualified was not obvious from the original Complaint, as the agency appeared to contend in its Motion to Dismiss, the suppliers stated it explicitly in MLTAC-1, ¶ 7. App. a65-66. The agency nevertheless opposed the motion for leave to amend.

MLTAC-1 ¶ 7 and MLTAC-3 ¶ 7 (*id.* and App. a99-a100) added further allegations of risk of harm as bases for standing. These were (1) that suppliers ran the risk of expending significant resources in going through the complex process of being accredited and submitting bids without knowing what the financial standards were, when, if they knew, they would be able to ascertain whether they could qualify and therefore could save those expenditures if it was apparent they could not qualify; (2) that the financial standards would impact the bids the suppliers would be willing to submit and therefore could affect whether they would submit a winning bid; (3) that they ran the risk of being excluded on an arbitrary and capricious basis if the required financial standards do not in fact exist; and (4) that inappropriate or non-existent financial standards would create the risk that financially unsound companies that should not have qualified would taint the bidding pool and undercut the Plaintiff suppliers' bids, resulting in their inability to

obtain contracts. "[I]llegal structuring of a competitive environment injures those who are regulated in that environment" and confers standing. Shays v. Fed. Election Comm'n, 414 F.3d 76, 85 (D.C. Cir. 2005) (and cases cited).

Finally, MLTAC-3 proposed to add a DME beneficiary plaintiff in a Round 2 area, Ms. Sopko, and ¶ 7 stated that that beneficiary faced the risk that with inappropriate financial standards, or no standards at all, she faced the risk of having to obtain her DME from a supplier who would provide a lower quality of service. App. a100. The requirement for financial standards was intended by Congress to ensure maintenance of DME supplies and quality of service, and therefore Ms. Sopko has a concrete interest in seeing that the Congressional mandate is properly implemented. *See Int'l Brotherhood of Teamsters v. Pena*, 17 F.3d 1478, 1484 (D.C. Cir. 1994) (notice and comment case; "[A] party within the zone of interest of any substantive authority generally will be within the zone of interests of any procedural requirement governing exercise of that authority, at least if the procedure is intended to enhance the quality of the substantive decision."). This beneficiary interest was recognized by the agency in its NPRM when it stated, "we believe that financial standards for suppliers will help maintain beneficiary access to quality services." 71 Fed. Reg. at 25675 2d col.

The district court's pronouncements on the lack of standing are unsupported. Its position that any harm to plaintiffs would be "self-inflicted" is contrary to the

concept of adequate notice and comment puzzling and the need for compliance with legislative mandates. Its apparent conclusion that notice and comment requirements were not designed to protect the plaintiffs is incorrect. Its conclusion that there is no showing of causation appears to be based on the incorrect notion that causation must be actual at this time rather than imminent or threatened. Its conclusion that adequate notice and comment could not transform a non-viable candidate into a viable candidate is contrary to the holding in Sugar Cane Growers Coop., 289 F.3d at 94-95, that "[a] plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. Finally, the district court's conclusion that the risks threatened by the lack of adequate notice and comment and failure to specify financial standards are too speculative is contrary to this Circuit's doctrine of self-evident standing when a plaintiff is the object of the regulatory action at issue.

III. The agency failed to provide adequate notice and meaningful opportunity for comment on a proposal for specifying financial standards, and the "general principles" in the preamble to the final rule were never proposed as "standards" and therefore could not have been the "logical outgrowth" of a proposal. Moreover, they were not a part of the substantive final rule.

In two recent decisions, the Supreme Court restated and clarified the standards of review for dismissal of a complaint on grounds of failure to state a claim upon which relief can be granted. Ashcroft v. Iqbal, 556 U.S. 662 (2009);

Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). Under those decisions, a claim passes 12(b)(6) muster if the claim is "plausible" and supported by sufficient alleged facts, accepted as true, from which it can be inferred that the claim is plausible. "A pleading must contain a 'short and plain statement of the claim showing that the pleader is entitled to relief.'" Iqbal, 556 U.S. at ____, 129 S.Ct. at 1949 (quoting from Twombly). The pleading standard "does not require 'detailed factual allegations,' but it demands more than an unadorned the defendant unlawfully-harmed-me accusation." *Id.* "Determining whether a complaint states a plausible claim for relief will ... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Iqbal, 556 U.S. ____, 129 S. Ct. at 1950.

In deciding a 12(b)(6) motion to dismiss, a court "'construes the complaint liberally in the plaintiff's favor,' 'accept[ing] as true all of the factual allegations contained in the complaint,' and granting the plaintiff 'the benefit of all reasonable inferences from the facts alleged.'" Aktieselskabet AF 21 Nov. 2001 v. Fame Jeans, Inc., 525 F.3d 8, 83 (D.C. Cir. 2008) (internal citations omitted).

- A. It is apparent from the administrative record facts set out in the Complaint that the agency's proposed rulemaking did not contain any concrete proposal for financial standards, discussion of alternatives, or the agency's reasoning, particularly with regard to the needs of small providers, and therefore it did not satisfy APA standards.**

A rulemaking proposal must present an actual, detailed proposal, supported by reasoning and discussion of alternatives in order to allow for meaningful comment. The agency cannot simply invite comment on an issue without making a proposal. Moreover, even when a proposal is presented, it can be too general to be adequate. The proposal "must describe the range of alternatives being considered with reasonable specificity." Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Admin., 494 F.3d 188, 209 (D.C. Cir. 2007) (the proposal sufficiently outlined five specific options, one of which forecast the final rule). *Cf.* Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 549 (D.C. Cir. 1983) (the proposal was too general to be adequate because it did not "describe the range of alternatives being considered with reasonable specificity.") The NPRM "must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." Cement Kiln Recycling Coal v. EPA, 493 F.3d 207, 225 (D.C. Cir. 2007). *Accord*, Honeywell Int'l, Inc. v. EPA, 372 F.3d 441, 445 (D.C. Cir. 2004); Fla. Power & Light Co. v. United States, 846 F.2d 765, 771 (D.C. Cir. 1988). A rulemaking proposal "must include sufficient detail on its content and basis in law and evidence to allow for meaningful and informed comment" and "adversarial critique." Am. Med Ass'n v. Reno, 57 F.3d 1129, 1132-33 (D.C. Cir. 1995). The agency must "make its views known to the public in a concrete and focused form." Home Box Office, Inc. v. FCC, 567 F.2d

9, 36 (D.C. Cir. 1977). It must "provide an accurate picture of the reasoning that has led the agency to the proposed rule." Conn. Light and Power Co. v. NRC, 673 F.2d 525, 530 (D.C. Cir. 1982).

In the present case, the Complaint set out the key portions of the agency's only rulemaking proposal in ¶¶ 13 and 14. App. a9-a10. The NPRM preamble section on financial standards" did not present any proposed standards. It stated only that "RFBs will identify the specific information we will require to evaluate suppliers, which may include We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards." 71 Fed. Reg. at 25675 2d col.

Not only did the preamble not present a proposal for standards, it stated that the agency was still developing a "methodology" for such standards that was undisclosed. The NPRM stated, "As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process." 71 Fed. Reg. at 25675 2d col. Such a failure to reveal the "methodology" underlying a rulemaking proposal is analogous to the failure to disclose technical data or studies underlying a proposal, which this Court has deemed a "serious procedural error." Conn. Light and Power Co. v. NRC, 673 F.2d 525, 530-31 (D.C. Cir. 1982).

While the preamble indicated that the RFB would identify specific information to be required, there was no indication that the RFB would contain standards for evaluating that information. Moreover, the RFB was not a part of the NPRM, and apparently was not published on the Internet until May 15, 2007, after the final rulemaking. App.a158.¹³ At any rate, as this Court has stated: "This court has never found that Internet notice is an acceptable substitute for publication in the Federal Register, and we refuse to do so now." Utility Solid Waste Activities Group v. EPA, 236 F.3d 749, 754 (D.C. Cir. 2001).

Moreover, although the NPRM recognized that the vast majority of DME suppliers were small businesses, there was no discussion in the notice in accordance with the statutory mandate to specify financial standards "taking into account the needs of small providers."

The substantive portion of the NPRM likewise did not contain any proposal for financial standards; it only stated, in proposed § 414.414 (d): "*Financial standards*. All suppliers must meet the applicable financial standards specified in the request for bids."

The district court opinion did not discuss the above case law applicable to rulemaking proposals, and it appeared to assume that it was sufficient that suppliers knew the issue existed and for the agency to simply invite comment on

¹³ It appears that there was never a stand-alone document titled the Request for Bids. Instead, it appears that the RFB was considered to be the RFB Instructions..

the issue without proposing anything in the way of standards (especially taking into account the needs of small businesses), and that requirements for submission of financial information could constitute financial standards. (*E.g.*, App. a145-a146: "[T]here can be no serious dispute that that plaintiffs were given an adequate opportunity to comment [The NPRM indicated the type of information that might be used] and invited comments and suggestions concerning these standards.")

B. The final "financial standards" that the court found to be adequate -- apparently "broad principles" of "overall financial soundness" or "financial viability" -- cannot be considered a "logical outgrowth" of the rulemaking proposal because they were never proposed, and were only stated in the preamble to the final rule. In addition, the agency and its CBIC have indicated that they are applying financial standards not proposed or disclosed in the rulemaking.

It has long been established that a final rule must be the "logical outgrowth" of a proposed rule. Env'tl. Integrity Project v. EPA, 425 F.3d 992, 996 (D.C. Cir. 2005) (collecting cases). In this case, it is not clear what the court determined were the final "financial standards" that were a "logical outgrowth" of the proposed rule. On the one hand, the district court refers to the various financial ratios (*e.g.*, debt-to-equity) that the agency indicated it "might" use (72 Fed. Reg. at 18038) as "standards" (App. a146), as having been subjected to adequate notice and comment. On the other hand, the district court refers to such financial ratios (correctly -- since the ratios are simply data that vary from company to company)

as "information" (App. a148), and as "interpretive rules" (App. a151 n.18). The district court never actually states with specificity what it regards as the financial standards that were legitimately adopted, but it refers repeatedly to some standards other than the financial ratios that it describes with language such as "the general standard," the "general, flexible standard," and the "broadly worded standard" (App. a149), "broad principles" (App. a148, a151), and, in its Conclusion, "a broad-based test for financial viability" (App. a156). Considering the above portions of the opinion together, it appears that when the district court stated that "the Court concludes that the Secretary's notice and request for comment on these broad principles ... violates neither APA 5 U.S.C. § 553 nor 42 U.S.C. § 1395hh ..." (App. a151) it is referring to the statement in the final rule that "We will be reviewing all financial information in the aggregate and not be basing our decision on one ratio but rather overall financial soundness" (72 Fed. Reg. at 18038), and that "overall financial soundness" (or "financial viability," *id.*) is the "broadly worded standard" or "broad principles" that it upheld as sufficient "standards."

One fatal error with the district court conclusion on this "broad principle," or anything like it, is that it was not proposed as a "financial standard" in the NPRM; it only appeared in the preamble to the final rule. The NPRM only proposed requiring certain types of financial information, and stated that the agency was still working on developing a "methodology" for such information, and invited

comment on "the financial standards." (71 Fed. Reg. at 25675, Compl. ¶ 13, App. a9). As stated in Kooritzky v. Reich, 17 F.3d. 1509, 1513 (D.C. Cir. 1994), "Something is not a logical outgrowth of nothing." The notice of proposed rulemaking contained nothing to suggest that the agency might adopt as a final rule specifying financial standards the "general principle" that was in the preamble to the final rule. Such a principle was "neither discussed nor mentioned" (*id.*) in the NPRM. And see 42 U.S.C. 1395hh(4) (a final rule must be the logical outgrowth of a proposal or else must be subjected to further notice and comment).

The district court also erred in not recognizing that the agency admittedly was withholding some sort of standards that had never been proposed in rulemaking. The NPRM stated that the agency was developing a "methodology" to evaluate the information it would require to be submitted, but no "methodology" has ever been disclosed, whether in rulemaking or otherwise. Both the agency and the district court admit that the agency has standards it is applying that have never been publicly disclosed. The district court quoted the agency (App. a149) as admitting that it has a financial qualification "cutoff" that it is employing but that it will not disclose. The RFB Instructions state that all bidders must meet "established financial thresholds" that are never stated. App. a 161. The district court quoted Mr. Weems of CMS as telling a Congressional subcommittee that the agency has not "disclosed ... exactly how we use the financial ratios [sic] in

judging the financial viability of each bidder We have told them the ratios that we would use, but we have not told them how that would be scored." App. a150. Then there are the Round 1 rebid bid rejection forms, which the suppliers attempted to introduce into the case via MLTAC-1, ¶ 21 (App. a72), and MLTAC-3, ¶ 22 (App. a106) of the proposed amended Complaints. Those forms indicate that CMS and its CBIC (Palmetto) are calculating a "financial score" for bidders that they must meet. App. a 189. None of these standards (in the form of a "methodology," "threshold," "score" or "cutoff") have ever been exposed to notice and comment; nor are they even in the 2007 final rule (or subsequent interim final rule of 2009 or the recent final rule of 2011). Finally, the agency has, for more than seven months, failed to respond to a FOIA request for documents indicating how it calculates the "financial score" referred to in the Round 1 rebid bid rejection forms. App. a190, a193.

Furthermore, not only are the "broad principles" endorsed by the district court not a "logical outgrowth" of any rulemaking proposal, they are not even a part of the substantive final rule; they are only in the preamble to the final rule, and for that reason also cannot be considered a logical outgrowth. The preamble to a rule generally contains an explanation of the rule set out in the substantive portion of the rulemaking notice and in the Code of Federal Regulations, and does not constitute an "operative part" of the rule, Wyo. Outdoor Council v. U.S. Forest

Serv., 165 F.3d 43, 53 (D.C. Cir. 1999). *Accord*, Nat'l Wildlife Fed'n v. EPA, 286 F.3d 554, 569 (D.C. Cir. 2002). Rulemaking language contained in a preamble but not the substantive rule is a "legal nullity." Natural Res. Def. Council v. EPA, 559 F.3d 561, 565 (D.C. Cir. 2009). The substantive final rule on "financial standards" contains nothing in the way of any kind of "general principle" nor any mention of "overall financial soundness" or "financial viability;" it requires only submission of financial documents specified in the request for bids. 42 C.F.R. § 414.414(d).

IV. The agency has not “specified” “financial standards” in its regulations as required by 42 U.S.C. § 1395w-3(b)(2)(A)(ii). The final rule requires only the submission of certain financial documents to be specified in the RFB. Documents, and ratio information extracted from them, are not standards.

A court assessing whether an agency regulation complies with a federal statutory mandate applies the familiar two-step analytical framework from Chevron, USA, Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). This Court recently described that framework in Intermountain Ins. Serv. of Vail v. IRS, 650 F.3d 691, 701 (D.C. Cir. 2011), *petition for cert. filed* Nov. 16, 2011 (No. 11-663), as follows:

Employing "traditional tools of statutory construction," ... we begin our Chevron analysis by "determin[ing] whether Congress has unambiguously foreclosed the agency's statutory interpretation." ... If it has not, then at Chevron's second step, we "ask[] whether the [agency] rule is a 'reasonable interpretation' of the enacted [statutory] text." [Internal citations omitted.]

A. Congress has "unambiguously foreclosed the agency's statutory interpretation" in its final rule by the plain language of the statute. Financial documents are not financial "standards."

In interpreting a statute, the first step is to determine "whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." U.S. ex rel. Miller v. Bill Harbert Int'l Constr., 608 F.3d 871, 879 (D.C. Cir. 2010),), *cert. denied*, ___ U.S. ____, 131 S.Ct. 2443 (2011). Here, the statute requires the agency to "specify" financial "standards" that suppliers must meet. Falling well short of this statutory mandate, the agency has instead only indicated that certain financial documents are required, and has not specified financial standards.

"Standards," in the context of the statute, are measures that can be applied uniformly to all suppliers. A measurement standard such as a meter or a pound would be useless as a standard if the length or weight were not defined in a uniform manner. A "general principle" such as "overall financial soundness" is inherently non-uniform, arbitrary, and subject to abuse because it is not defined and its meaning can vary in application from one supplier to another. The requirement that the agency determine whether a supplier "meets" "applicable financial standards" would be meaningless if the agency could make *ad hoc* determinations of "financial soundness."

Common definitions of "standard" clearly require that a standard be a type of measurement capable of uniform application. BLACK'S LAW DICTIONARY (9th ed., 2009) defines "standard" as "1. A model accepted as correct by ... authority ... (2) A criterion for measuring acceptability" Non-legal dictionary definitions are similar. WEBSTER'S THIRD NEW INT'L DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED (2002) defines a "standard" (as relevant -- other than a banner, emblem, etc.) as "**3 a** : something that is established by authority ... as a model or example to be followed: CRITERION, TEST **b**: a definite level or degree of quality that is proper and adequate for a specific purpose **4**: something that is set up and established by authority as a rule for the measure of quantity, weight, extent, value, or quality" THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (5th ed. 2011) defines "standard" as "**1**. Serving as or conforming to an established or accepted measurement or value" And the NEW OXFORD AMERICAN DICTIONARY (3d ed. 2010) defines "standard" as "**1** a level of quality or attainment ... a required or agreed level of quality or attainment."

The submission of certain documents, as required by the agency rule, cannot provide any sort of model or criterion for measuring or attainment. And financial ratios derived from such documents are no more than a particular arrangement of company-specific data provided in the documents.

The agency's Internet announcement of the "Financial Measures" to be used in the Round 1 rebid and Round 2¹⁴ -- which is no more than a list of kinds of financial ratios without any measurement values associated with them (App. a162) -- confirms that they are not considered "standards," in stating, at the end, that "[t]hese ratios and the credit report and score are used to determine bidder compliance with financial standards." These CMS "financial measures" are, as they state, simply a list of "standard accounting ratios for each bidder" that are calculated for each bidder using the tax and financial documents it is required to submit. *Id.*

Inconsistently, the agency itself has interpreted almost identical language to require detailed and uniform criteria in order to suffice as "standards." The statutory provision immediately preceding the "financial standards" provision at issue states in almost identical language that an entity is not eligible for a DME contract unless it "meets applicable quality standards specified by the Secretary

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<http://www.dmecompetitivebid.com/palmetto/CBIC.nsf/DocsCat/CBIC~Bidding%20Suppliers%20Round%202%20National%20Mail-Order~Bid%20Evaluation~8P2K5N5878?open&navmenu=Bidding%5ESuppliers%5ERound%5E2%5ENational%5EMail-Order%7C%7C%7C%7C> (accessed Jan. 9, 2012). App. a162. The "financial measures" list of ratios has changed somewhat since the Round 1 rebid (without rulemaking). *Cf.* <http://www.dmecompetitivebid.com/cbic/cbicrd1.nsf/DocsCat/852573EE00644C008525763B0073EAB3?Open&cat=Suppliers~Bid%20Evaluation> (2009 version, accessed Jan. 9, 2012). However the statement regarding "compliance with financial standards" has not changed.

..." 42 U.S.C. § 1395w-3(b)(2)(A)(i); 42 C.F.R §414.414(c). The agency's quality "standards" (which Congress expressly exempted from notice-and-comment rulemaking,¹⁵ unlike the financial standards) consist of pages of concrete, detailed, objective requirements that all, or certain types of, DME suppliers must meet in order to be accredited.¹⁶ App. a163-a186. The agency did not simply specify information that would be looked at for each supplier's business in order to make a decision regarding overall quality.

The agency has also set concrete, objective "financial solvency and capital adequacy standards" for Medicare+Choice provider-sponsored organizations under 42 U.S.C. §§ 1395w-25(c) and 26(a). Those standards include minimum net worth requirements, cash-flow liquidity to meet current obligations, and a specific insolvency security deposit. 42 C.F.R §§ 380-390.

It is also relevant to consider how other agencies have interpreted "financial standards" or similar standards language for regulating entities to ensure their financial soundness. The Commodities Futures Trading Commission is required to set "minimum financial requirements" for futures commission merchants and

¹⁵ 42 U.S.C. § 1395m(a)(2), referenced in the quality standards provision, states, in para. (E), that the agency "may establish by program instruction or otherwise the quality standards under this paragraph, Such standards ... shall be published on the Internet website of the Centers for Medicare & Medicaid Services."

¹⁶

https://www.cms.gov/MLNProducts/downloads/DMEPOS_Qual_Stand_Booklet_I_CN905709.pdf (accessed Jan. 9, 2012).

introducing brokers. 7 U.S.C. § 6f(b). The CFTC regulations set requirements for the dollar amount of "adjusted net capital" that merchants and brokers must maintain, and "net capital" is defined as the amount by which current assets exceed liabilities (similar to a debt/equity ratio). 17 C.F.R. § 1.17(a) and (c). The Securities and Exchange Commission sets financial requirements for brokers and dealers. Among those requirements are its "Ratio Requirements," and the ratio for the "aggregate indebtedness standard" requires that aggregate indebtedness shall not exceed "1500 percent of its net capital (or 800 percent of its net capital for 12 months after commencing business)." 17 C.F.R § 240.15c3-1(a). In other words, this "standard" does not require simply submitting information on ratio of debt to capital; it requires that debt not exceed capital by a definite percentage. Likewise, the Department of Education specifies "financial responsibility standards" that institutions of higher education must meet in order to qualify for federal student aid ("FSA"). 20 U.S.C. § 1099c(c); 34 C.F.R § 668.15. Under those standards, institutions do not just submit "ratio" information; they are required to "meet criteria prescribed by the Secretary regarding ratios that demonstrate financial responsibility." Private nonprofit schools must also meet a financial "score" determined under guidance promulgated by the Department. See the Department's *FSA Handbook*, vol. 2, ch. 4, pp. 2-61 to 2-70 (April 2011).¹⁷

¹⁷ <http://ifap.ed.gov/fsahandbook/attachments/1011FSAHbkVol2Ch4.pdf>.

The Department of Agriculture's crop insurance program oversees the financial viability of crop insurers and requires them to meet specific "ratio requirements" -- *e.g.*, a "Gross Premium to Surplus" ratio of "Less than 900%" and at least 10 of 14 other ratios that include, *e.g.*, a "quick liquidity" ratio of "Greater than 20%." 7 C.F.R §400.170(d). To ensure the viability of depository institutions, the Federal Deposit Insurance Corporation must set a specific "Minimum Reserve Ratio" each year that is not "less than 1.35 percent of estimated insured deposits" or a "comparable percentage" based on designated considerations. 12 U.S.C. § 1817(b)(3)(B).¹⁸

In considering the plain language of the statutory mandate, the fact that "standards" is stated in the plural form is also significant. More significant is the use of the word "specified." That term (under "specify") is defined in WEBSTER'S THIRD INT'L DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED (2002) as "**1 a** : to mention or name in a specific or explicit manner : tell or state precisely or in

¹⁸ The FDIC is also required to set "standards for safety and soundness" of insured depository institutions, either by regulation or guideline. 12 U.S.C. § 1831p-1. The FDIC and other banking agencies have elected to promulgate inter-agency "guidelines" for such standards. 12 C.F.R § 364.100. Those guidelines do not contain numerical ratios or other numerical standards, but they are nevertheless very detailed and go far beyond simply requiring the submission of certain information by institutions or consideration of something like a general principle of "overall [financial] safety and soundness."

detail."¹⁹ The AMER. HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (5th ed. 2011) defines "specify" and "specified" as "1. To state explicitly or in detail" The NEW OXFORD AMERICAN DICTIONARY (3d ed. 2010) defines "specify" and "specified" as "identify clearly and definitely" and "state a fact or requirement clearly and precisely"

The agency cannot seriously contend that it has "specified" financial "standards" by publishing a rule that requires only that suppliers submit documents. Documents are not standards; they can only provide information to be used in determining compliance with specific standards. The district court failed to analyze the specific wording of the statute and consider Chevron step one in finding that the agency had complied with the statute.

B. Even if the principle of "overall financial soundness" in the final rule's preamble could somehow be regarded as a specific "standard," such a "standard" cannot be considered permissible under Chevron step two because it is too vague, general, and arbitrary.

Although, as the district court states, an agency has broad discretion to set standards when Congress has not defined the level of specificity required, that

¹⁹ *And see* Kucana v. Holder, 558 U.S. _____, 130 S. Ct. 827, 834 n. 10 (2010) (commenting on the significance of the term "specified" as distinguished from "implied," and quoting the definition of "specify" from WEBSTER'S NEW COLLEGIATE DICTIONARY (1974): "to name or state explicitly or in detail"). *See also* Gaddis v. United States, 381 F.3d 444, 466 (5th Cir. 2004) (quoting the definition of "specifically" from WEBSTER'S THIRD NEW INT'L DICTIONARY (1986) as "with exactness and precision: in a definite manner."

discretion is not unlimited. Under Chevron's second step, the Court must determine "whether the [agency] rule is a 'reasonable interpretation' of the statutory language. Intermountain Ins. Serv. of Vail, 650 F.3d at 701.

Although the deference given the agency is "indulgent" under this step, an agency rule can be "so vague as to make the rule meaningless." Oceana, Inc. v. Locke, ___ F.3d ____, 2011 WL 2802989 (D.C. Cir. 2011). In Oceana, this Court determined that the agency's rule was "so vague as to make the rule meaningless" because the rule imposed no constraint on the agency's discretion (at *3), doing "little to channel the agency's exercise of discretion," and recited factors to consider that "merely restate the agency's statutory obligations." At *4. The Court in Oceana distinguished that case from its decision in Cement Kiln Recycling Coalition v. EPA, 493 F.3d 207 (D.C. Cir. 2007), finding that the agency rule, although vague, contained an "'identifiable standard'" to guide its judgment. Cement Kiln, 493 F.3d at 220-21. Such an "identifiable standard" is not present in this case. And in MST Express v. DOT, 108 F.3d 401, 406 (D.C. Cir. 1997) this Court found agency safety regulations did not satisfy the statutory mandate to regulate because they "merely provide that a carrier's rating will be based upon the degree to which its safety management controls are 'adequate,' which the regulations define only as 'appropriate for the size and type of operation of the particular motor carrier.'" MST Express is thus very analogous to the present case,

in which the district court determined that a "general principle" of "overall financial soundness" for a particular supplier was a sufficient standard.

C. The agency and its CBIC have admitted that they are intentionally withholding the actual financial standards being applied to the documentation, thereby conceding that their rule does not specify the required standards.

Before Congress (App. a150), before the district court (App. a149, a21-a24), in its final rule, in its RFB Instructions (App. a161), and in documents sent to Round 1 rebid bidders whose bids were rejected (App. a189), as previously discussed, the agency (or its CBIC) indicated that it is using some sort of financial standards, "scoring," "threshold," or "cutoff" that it has not disclosed in its regulations and which have not been exposed to notice and comment.

In its opinion the district court quoted from the agency's Motion to Dismiss a section in which the agency's counsel explained that that they were not disclosing their financial standards because "[a]rmed with the knowledge of CMS's minimum financial qualification standards, firms in danger of falling below CMS's cutoff" could manipulate the information they provided to make it over the qualification threshold. App. a149.

In the preamble to its 2008 final rule, the agency stated that "[i]f suppliers do not meet **certain** ratios, they could be disqualified from the competition." 72 Fed. Reg. at 18038 1st col. (emphasis added).

As referenced in the district court opinion (App. a150), Mr. Kerry Weems of CMS informed a Congressional subcommittee at a hearing that the agency "had not 'disclosed ... exactly how we use the financial ratios [sic] in judging the financial viability of each bidder We have told them the ratios that we would use, but we have not told them how that would be scored.'" Furthermore, when Palmetto (the agency's CBIC) informed suppliers that their Round 1 rebid bids had been rejected, the forms they provided contained a column that could be checked (as a reason for rejection) indicating that the agency calculated a "financial score" that the supplier had failed to meet. App. a189. Subsequent to receiving such a form, Texas Medical, Inc. submitted a FOIA request to the agency requesting any documents indicating how they calculated a "financial score," and has not received a response after more than seven months. App. a190, a193.

The agency has no authority to withhold the standards (or "score", "threshold," or "cutoff") that it is employing as a financial standard that suppliers must meet. Potential fraud is not a legally justifiable rationale for not providing adequate notice and comment and withholding the actual standards being applied. The potential for submission of fraudulent information could always be cited as a reason for not disclosing mandated standards.²⁰ But there are already ample laws against fraud, and Congress has not authorized the agency to withhold its

²⁰ Also, many of the required financial documents -- such as a credit score, tax abstracts, and SEC filings -- are not capable of falsification as a practical matter.

standards; instead, it has mandated that they be "specified." And see 42 U.S.C. § 1395hh. If the agency believes the standards should not be disclosed, it must seek Congressional approval to withhold them.

D. The final rule violates APA requirements by not stating the agency's reasoning ("basis and purpose") for adopting the final rule.

In adopting a final rule, an agency must "articulate with reasonable clarity its reasons for decision, and identify the significance of the crucial facts." Amer. Med. Ass'n v. Reno, 57 F.3d 1129, 1133 (D.C. Cir. 1995). The agency has not explained why it did not adopt, and disclose, specific standards in the form of uniform measures or models and only required submission of certain documents and information.

E. Congress did not ratify the preamble "general principle" approved by the district court as an adequate financial standard.

The district court gave only one example of a statement specifically relevant to a disclosure to Congress about its utilization of financial standards. That statement was the one by Mr. Kerry Weems quoted above and by the district court. App. a150. But a single statement before a subcommittee is not sufficient to put Congress on notice of an agency "interpretation" of its mandate and support an assertion of Congressional ratification on re-enactment.

Congressional ratification of an agency interpretation requires far more.

The agency interpretation must be long-standing, well-recognized, and publicly controversial. The doctrine of Congressional ratification by re-enactment "requires a showing of both congressional awareness and 'express congressional approval ...'" Gen. Amer. Transp. Corp. v. ICC, 872 F.2d 1048, 1053 (D.C. Cir. 1989). *And see* AFL-CIO v. Brock, 835 F.2d 912, 915-16 (D.C. Cir. 1987). There is no indication of Congressional approval of an agency interpretation of specification of financial standards to allow for only a "general principle of "overall financial soundness" and withholding of the methodology for evaluating the required financial documentation and the ratios extracted from that documentation. There is also no indication that Mr. Weem's single statement put Congress, as a body, on notice of an agency interpretation that could be considered controversial. Mr. Weem's statement that the agency had disclosed the financial ratios they use, but not how they are used to calculate a score and to determine financial viability, did not state that there was any controversy regarding compliance with a Congressional mandate; in fact, he implied that everything was being done in accordance with the statute.

The doctrine that repeals by implication are not favored also comes into play here. If Mr. Weem's statement that the agency was not disclosing how a supplier would be "scored" using its company-specific financial ratios were considered a statement that the agency was intentionally violating the Congressional mandate

for specification of standards and disclosure through rulemaking as required by the APA, 5 U.S.C. § 553(b) and (c), and by 42 U.S.C. § 1395hh, Congressional ratification of such non-compliance would amount to a repeal by implication. Such a notion is obviously unsupportable, since repeals by implication are "strongly disfavored 'absent a clearly expressed congressional intention.'" Village of Barrington, Ill. v. Surface Transp. Bd., 636 F.3d 650, 661-662 (D.C. Cir. 2011).

CONCLUSION AND REQUEST FOR RELIEF

This Court has subject matter jurisdiction because there is no clear and convincing evidence whatever that Congress intended to preclude judicial review of the notice and comment and statutory mandate issues in this case, and because the appellant suppliers have Article III standing as entities directly subject to the regulations at issue. The proposed beneficiary plaintiff would also have standing as a person the notice and comment procedures and financial standards were intended to protect.

The final rules promulgated by the agency did not comply with the notice and comment requirements of the APA and the Medicare Act because the "general principles" relied on by the district court were never proposed as standards, and the standards (scoring, thresholds, cutoffs, and specific ratio values) were never proposed and never disclosed. Moreover, the agency interpretation of "standards" is non-compliant with the statutory mandate because it is essentially standardless in

giving the agency complete discretion as to its application on a case-by-case basis. The agency rulemaking on financial standards has been not in accordance with law and has been conducted without procedures required by law. 5 U.S.C. § 706.

The Appellants request that this Court redress the above agency non-compliance by (1) vacating the existing rulemaking on financial standards and remanding to the agency to conduct a new proposed and final rulemaking with adequate notice and opportunity for comment on specific financial standards; (2) declaring that in order to comply with the Congressional mandate the agency must promulgate rules specifying actual standards for evaluating the financial soundness of suppliers, taking into account the needs of small providers, that are capable of uniform application and are reasonable, and with an adequate explanation of the agency's reasoning underlying the final standards; and (3) granting the Third Motion for Leave to Amend the Complaint.

Respectfully submitted,

January 23, 2012

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief, using Times New Roman 14-point font, contains 13,849 words according to the word count provided by Microsoft Word 2003. The text of the brief complies with the type-volume limitations, typeface requirements, and type style requirements of Federal Rules of Appellate Procedure 32(a) and D.C. Circuit Rule 32(a).

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CERTIFICATE OF SERVICE

I hereby certify that on January 23, 2012, I caused a copy of the foregoing Brief for the Appellants and the Appendix to Appellants' Brief to be filed with the Clerk of the United States Court of Appeals for the District of Columbia Circuit by using the Court's appellate CM/ECF system. I also certify that I will cause eight paper copies to be delivered to the Clerk of the Court via FedEx Standard Overnight[®] service, or equivalent, within two business days. Service will be made upon the following counsel for Appellees also via the CM/ECF system, with two paper copies to each within two business days via the same means.

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STATUTORY AND REGULATORY ADDENDUM

**STATUTORY AND REGULATORY ADDENDUM
TO APPELLANTS' BRIEF**

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same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law.

(3) The Secretary shall develop and implement specific procedures with respect to when and how each of the intermediate sanctions developed under paragraph (1) is to be applied, the amounts of any penalties, and the severity of each of these penalties. Such procedures shall be designed so as to minimize the time between identification of violations and imposition of these sanctions and shall provide for the imposition of incrementally more severe penalties for repeated or uncorrected deficiencies.

(Aug. 14, 1935, ch. 531, title XVIII, § 1846, as added Pub. L. 100-203, title IV, § 4064(d)(1), Dec. 22, 1987, 101 Stat. 1330-111; amended Pub. L. 100-360, title II, § 203(e)(4), title IV, § 411(g)(3)(G), July 1, 1988, 102 Stat. 725, 784; Pub. L. 100-485, title VI, § 608(d)(22)(C), Oct. 13, 1988, 102 Stat. 2421; Pub. L. 101-234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101-508, title IV, § 4154(e)(2), Nov. 5, 1990, 104 Stat. 1388-86.)

AMENDMENTS

1990—Pub. L. 101-508 substituted “providers or suppliers of” for “providers of” in section catchline.

1989—Pub. L. 101-234 repealed Pub. L. 100-360, § 203(e)(4), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment notes below.

1988—Pub. L. 100-360, § 203(e)(4)(A), inserted “and for qualified home intravenous drug therapy providers” at end of section catchline.

Subsec. (a). Pub. L. 100-360, § 411(g)(3)(G)(i)(D), as amended by Pub. L. 100-485, substituted “approved” for “certified”.

Pub. L. 100-360, § 411(g)(3)(G)(i)(II), inserted “or for coverage” after “conditions of participation”.

Pub. L. 100-360, § 411(g)(3)(G)(i)(III), which directed amendment of subsec. (a) by substituting “terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory” for “cancelling immediately the certification of the provider or clinical laboratory”, was executed by making the substitution for “canceling immediately the certification of the provider or clinical laboratory” to reflect the probable intent of Congress.

Pub. L. 100-360, § 203(e)(4)(B), inserted “or that a qualified home intravenous drug therapy provider that is certified for participation under this subchapter no longer substantially meets the requirements of section 1395x(jj)(3) of this title” after “under this part”.

Subsec. (b)(1)(A). Pub. L. 100-360, § 411(g)(3)(G)(ii), struck out “certified” before “clinical laboratories”.

Subsec. (b)(2)(A). Pub. L. 100-360, § 411(g)(3)(G)(iv), inserted at end “The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.”

Subsec. (b)(2)(A)(ii). Pub. L. 100-360, § 411(g)(3)(G)(iii), substituted “civil money penalties in an amount not to exceed \$10,000 for each day of substantial noncompliance” for “civil fines and penalties”.

Subsec. (b)(2)(A)(iii). Pub. L. 100-360, § 411(g)(3)(G)(v), struck out “certification” before “surveys”.

Subsec. (b)(2)(A)(iv). Pub. L. 100-360, § 411(g)(3)(G)(ii), (vi), struck out “certified” before “clinical laboratory” and substituted “furnished on or after the date on” for “provided on or after the date in”.

Pub. L. 100-360, § 203(e)(4)(C), inserted “or home intravenous drug therapy services” after “clinical diagnostic laboratory tests”.

Subsec. (b)(3). Pub. L. 100-360, § 411(g)(3)(G)(vii), substituted “any penalties” for “any fines” and “severe penalties” for “severe fines”.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-508 effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, see section 4154(e)(5) of Pub. L. 101-508, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101-234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101-234, set out as a note under section 1320a-7a of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100-485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100-360, see section 608(g)(1) of Pub. L. 100-485, set out as a note under section 704 of this title.

Amendment by section 203(e)(4) of Pub. L. 100-360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100-360, set out as a note under section 1320c-3 of this title.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(g)(3)(G) of Pub. L. 100-360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, effective as if included in the enactment of that provision in Pub. L. 100-203, see section 411(a) of Pub. L. 100-360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Section 4064(d)(2) of Pub. L. 100-203 provided that: “The amendment made by paragraph (1) [enacting this section] shall become effective on January 1, 1990.”

§ 1395w-3. Competitive acquisition of certain items and services

(a) Establishment of competitive acquisition programs

(1) Implementation of programs

(A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) Phased-in implementation

The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs**(i) Round 1 of competitive acquisition program**

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

(I) the contracts awarded under this section before July 15, 2008, are terminated, no payment shall be made under this subchapter on or after July 15, 2008, based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs

In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG

The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation**(i) In general**

In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date

The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process

The process provided under this subparagraph—

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined

In this subparagraph, the term “covered document” means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(2) Items and services described

The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies

Covered items (as defined in section 1395m(a)(13) of this title) for which payment would otherwise be made under section 1395m(a) of this title, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).

(B) Other equipment and supplies

Items and services described in section 1395u(s)(2)(D) of this title, other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics

Orthotics described in section 1395x(s)(9) of this title for which payment would otherwise be made under section 1395m(h) of this title which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority

In carrying out the programs under this section, the Secretary may exempt—

(A) rural areas and areas with low population density within urban areas that are

not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen

In the case of a covered item for which payment is made on a rental basis under section 1395m(a) of this title and in the case of payment for oxygen under section 1395m(a)(5) of this title, the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1395m(a) of this title.

(5) Physician authorization

(A) In general

With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount

A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

(6) Application

For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) of this section shall be substituted for the payment basis otherwise applied under section 1395m(a) of this title, section 1395m(h) of this title, or section 1395u(s) of this title, as appropriate.

(7) Exemption from competitive acquisition

The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics

Items and services described in paragraph (2)(C) if furnished—

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment

Those items and services described in paragraph (2)(A)—

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

(b) Program requirements

(1) In general

The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) of this section for each competitive acquisition area in which the program is implemented under subsection (a) of this section with respect to such items and services.

(2) Conditions for awarding contract

(A) In general

The Secretary may not award a contract to any entity under the competition conducted in an¹ competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1395m(a)(20) of this title.

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(B) Timely implementation of program

Any delay in the implementation of quality standards under section 1395m(a)(20) of this title or delay in the receipt of advice from the program oversight committee established under subsection (c) of this section shall not delay the implementation of the competitive acquisition program under this section.

(3) Contents of contract

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) Term of contracts

The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) Disclosure of subcontractors

(i) Initial disclosure

Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form

and manner specified by the Secretary, the information on—

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1395m(a)(20)(F)(i) of this title, if applicable to such subcontractor.

(ii) Subsequent disclosure

Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) Limit on number of contractors

(A) In general

The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

(B) Multiple winners

The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

(5) Payment

(A) In general

Payment under this part for competitively priced items and services described in subsection (a)(2) of this section shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) Reduced beneficiary cost-sharing

(i) Application of coinsurance

Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) Application of deductible

Before applying clause (i), the individual shall be required to meet the deductible described in section 1395l(b) of this title.

(C) Payment on assignment-related basis

Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) Construction

Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

¹ So in original. Probably should be "a".

(6) Participating contractors**(A) In general**

Except as provided in subsection (a)(4) of this section, payment shall not be made for items and services described in subsection (a)(2) of this section furnished by a contractor and for which competition is conducted under this section unless—

- (i) the contractor has submitted a bid for such items and services under this section; and
- (ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) Bid defined

In this section, the term “bid” means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) Rules for mergers and acquisitions

In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) Protection of small suppliers

In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) Consideration in determining categories for bids

The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) Authority to contract for education, monitoring, outreach, and complaint services

The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

(9) Authority to contract for implementation

The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) Special rule in case of competition for diabetic testing strips**(A) In general**

With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip

products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

(B) Study of types of testing strip products

Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquisition² program described in subparagraph (A).

(11) No administrative or judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of—

- (A) the establishment of payment amounts under paragraph (5);
- (B) the awarding of contracts under this section;
- (C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);
- (D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);
- (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;
- (F) the bidding structure and number of contractors selected under this section; or
- (G) the implementation of the special rule described in paragraph (10).

(c) Program Advisory and Oversight Committee**(1) Establishment**

The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the “Committee”).

(2) Membership; terms

The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) Duties**(A) Advice**

The Committee shall provide advice to the Secretary with respect to the following functions:

- (i) The implementation of the program under this section.
- (ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii) of this section.

² So in original. Probably should be “acquisition”.

(iii) The establishment of requirements for collection of data for the efficient management of the program.

(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1395x(d) of this title), and individuals.

(v) The establishment of quality standards under section 1395m(a)(20) of this title.

(B) Additional duties

The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(4) Inapplicability of FACA

The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(5) Termination

The Committee shall terminate on December 31, 2011.

(d) Report

Not later than July 1, 2011, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

(e) Repealed. Pub. L. 110-275, title I, § 145(a)(1), July 15, 2008, 122 Stat. 2547

(f) Competitive acquisition ombudsman

The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1395b-9(c) of this title. The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1395b-9(c)(2)(C) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1847, as added Pub. L. 105-33, title IV, § 4319(a), Aug. 5, 1997, 111 Stat. 392; amended Pub. L. 106-113, div. B, § 1000(a)(6) [title III, § 321(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A-366; Pub. L. 108-173, title III, § 302(b)(1), Dec. 8, 2003, 117 Stat. 2224; Pub. L. 110-275, title I, §§ 145(a)(1), 154(a)(1), (b)(2), (3), (c)(2)(A), (B), (d)(1), (3), (4), July 15, 2008, 122 Stat. 2547, 2560, 2565-2568; Pub. L. 111-148, title VI, § 6410(a), Mar. 23, 2010, 124 Stat. 773.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(2)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Advisory Committee Act, referred to in subsec. (c)(4), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 1395w-3, act Aug. 14, 1935, ch. 531, title XVIII, § 1847, as added July 1, 1988, Pub. L. 100-360, title II, § 202(j), 102 Stat. 719; amended Oct. 13, 1988, Pub. L. 100-485, title VI, § 608(d)(5)(I), 102 Stat. 2414, provided for appointment of Prescription Drug Payment Review Commission by Director of Congressional Office of Technology Assessment, prior to repeal by Pub. L. 101-234, title II, § 201(a), (c), Dec. 13, 1989, 103 Stat. 1981, effective Jan. 1, 1990.

AMENDMENTS

2010—Subsec. (a)(1)(B)(i)(II). Pub. L. 111-148, § 6410(a)(1), substituted “91” for “70”.

Subsec. (a)(1)(D)(ii)(II), (III). Pub. L. 111-148, § 6410(a)(2), added subcl. (II) and redesignated former subcl. (II) as (III).

2008—Subsec. (a)(1)(B)(i). Pub. L. 110-275, § 154(a)(1)(A)(i), inserted “consistent with subparagraph (D)” after “in a manner” in introductory provisions.

Subsec. (a)(1)(B)(i)(II). Pub. L. 110-275, § 154(a)(1)(A)(ii), substituted “an additional 70” for “80” and “in 2011” for “in 2009”.

Subsec. (a)(1)(B)(i)(III). Pub. L. 110-275, § 154(a)(1)(A)(iii), substituted “after 2011 (or, in the case of national mail order for items and services, after 2010)” for “after 2009”.

Subsec. (a)(1)(D) to (F). Pub. L. 110-275, § 154(a)(1)(A)(iv), added subpars. (D) to (F).

Subsec. (a)(2)(A). Pub. L. 110-275, § 154(a)(1)(B), which directed amendment of par. (2)(A) of subsec. (a)(1) by inserting “and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs)” before period at end, was executed by making the insertion in subsec. (a)(2)(A), to reflect the probable intent of Congress.

Subsec. (a)(7). Pub. L. 110-275, § 154(d)(1), added par. (7).

Subsec. (b)(3)(C). Pub. L. 110-275, § 154(b)(2), added subpar. (C).

Subsec. (b)(10). Pub. L. 110-275, § 154(d)(3)(B), added par. (10). Former par. (10) redesignated (11).

Subsec. (b)(11). Pub. L. 110-275, § 154(d)(3)(A), redesignated par. (10) as (11).

Subsec. (b)(11)(C). Pub. L. 110-275, § 154(d)(4)(A), inserted “and the identification of areas under subsection (a)(1)(D)(iii)” after “(a)(1)(A)”.

Subsec. (b)(11)(D). Pub. L. 110-275, § 154(d)(4)(B), inserted “and implementation of subsection (a)(1)(D)” after “(a)(1)(B)”.

Subsec. (b)(11)(G). Pub. L. 110-275, § 154(d)(4)(C)-(E), added subpar. (G).

Subsec. (c)(5). Pub. L. 110-275, § 154(c)(2)(A), substituted “December 31, 2011” for “December 31, 2009”.

Subsec. (d). Pub. L. 110-275, § 154(c)(2)(B), substituted “July 1, 2011” for “July 1, 2009”.

Subsec. (e). Pub. L. 110-275, § 145(a)(1), struck out subsec. (e) which related to a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests, terms and conditions of the project, and reporting requirement.

Subsec. (f). Pub. L. 110-275, § 154(b)(3), added subsec. (f).

2003—Pub. L. 108-173 amended section catchline and text generally, substituting provisions relating to competitive acquisition of certain items and services for provisions relating to demonstration projects for competitive acquisition of items and services.

1999—Subsec. (b)(2). Pub. L. 106-113 inserted “and” after “specified by the Secretary”.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 154 of Pub. L. 110-275 effective June 30, 2008, see section 154(e) of Pub. L. 110-275, set out as a note under section 1395m of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106-113 effective as if included in the enactment of the Balanced Budget Act of 1997,

Pub. L. 105-33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106-113, set out as a note under section 1395d of this title.

GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION
ON SUPPLIERS

Pub. L. 108-173, title III, §302(b)(3), Dec. 8, 2003, 117 Stat. 2230, as amended by Pub. L. 110-275, title I, §154(c)(1), July 15, 2008, 122 Stat. 2565, provided that:

“(A) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act [this section], as amended by paragraph (1) and as amended by section 2 of the Medicare DMEPOS Competitive Acquisition Reform Act of 2008 [probably should refer to section 154 of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275], on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment and the topics specified in subparagraph (C).

“(B) REPORT.—Not later than 1 year after the first date that payments are made under section 1847 of the Social Security Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

“(C) TOPICS.—The topics specified in this subparagraph, for the study under subparagraph (A) concerning the competitive acquisition program, are the following:

“(i) Beneficiary access to items and services under the program, including the impact on such access of awarding contracts to bidders that—

“(I) did not have a physical presence in an area where they received a contract; or

“(II) had no previous experience providing the product category they were contracted to provide.

“(ii) Beneficiary satisfaction with the program and cost savings to beneficiaries under the program.

“(iii) Costs to suppliers of participating in the program and recommendations about ways to reduce those costs without compromising quality standards or savings to the Medicare program.

“(iv) Impact of the program on small business suppliers.

“(v) Analysis of the impact on utilization of different items and services paid within the same Healthcare Common Procedure Coding System (HCPCS) code.

“(vi) Costs to the Centers for Medicare & Medicaid Services, including payments made to contractors, for administering the program compared with administration of a fee schedule, in comparison with the relative savings of the program.

“(vii) Impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how such supplies are furnished.

“(viii) Such other topics as the Comptroller General determines to be appropriate.”

REPORT ON ACTIVITIES OF SUPPLIERS

Pub. L. 108-173, title III, §302(e), Dec. 8, 2003, 117 Stat. 2233, as amended by Pub. L. 110-275, title I, §154(c)(2)(C), July 15, 2008, 122 Stat. 2566, provided that: “The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act [this section], as amended by subsection (a) [probably should be (b)(1)], are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2011, the Inspector General shall submit to Congress a report on such study.”

STUDY BY GAO

Section 4319(c) of Pub. L. 105-33 provided that: “The Comptroller of the United States shall study the effectiveness of the establishment of competitive acquisition areas under section 1847(a) of the Social Security Act [subsec. (a) of this section], as added by this section.”

§ 1395w-3a. Use of average sales price payment methodology

(a) Application

(1) In general

Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1395u(o)(1)(C) of this title and that are furnished on or after January 1, 2005.

(2) Election

This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1395w-3b of this title for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e) of this section, the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C) of this section), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D) of this section), 106 percent of the amount determined under paragraph (4); or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) Specification of unit

(A) Specification by manufacturer

The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1396r-8(b)(3)(A)(iii) of this title.

(B) Unit defined

In this section, the term “unit” means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

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Public Law 108-173
108th Congress

An Act

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

Dec. 8, 2003
[H.R. 1]

Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
42 USC 1305 note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003”.

(b) **AMENDMENTS TO SOCIAL SECURITY ACT.**—Except as otherwise specifically provided, whenever in division A of this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

42 USC 1301 note.

(c) **BIPA; SECRETARY.**—In this Act:

(1) **BIPA.**—The term “BIPA” means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106-554.

(2) **SECRETARY.**—The term “Secretary” means the Secretary of Health and Human Services.

(d) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

- Sec. 101. Medicare prescription drug benefit.
- Sec. 102. Medicare Advantage conforming amendments.
- Sec. 103. Medicaid amendments.
- Sec. 104. Medigap amendments.
- Sec. 105. Additional provisions relating to medicare prescription drug discount card and transitional assistance program.
- Sec. 106. State Pharmaceutical Assistance Transition Commission.
- Sec. 107. Studies and reports.
- Sec. 108. Grants to physicians to implement electronic prescription drug programs.
- Sec. 109. Expanding the work of medicare Quality Improvement Organizations to include parts C and D.
- Sec. 110. Conflict of interest study.
- Sec. 111. Study on employment-based retiree health coverage.

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TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage program.

Subtitle B—Immediate Improvements

Sec. 211. Immediate improvements.

Subtitle C—Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition

Sec. 221. Establishment of MA regional plans.
Sec. 222. Competition program beginning in 2006.
Sec. 223. Effective date.

Subtitle D—Additional Reforms

Sec. 231. Specialized MA plans for special needs individuals.
Sec. 232. Avoiding duplicative State regulation.
Sec. 233. Medicare MSAs.
Sec. 234. Extension of reasonable cost contracts.
Sec. 235. Two-year extension of municipal health service demonstration projects.
Sec. 236. Payment by PACE providers for medicare and medicaid services furnished by noncontract providers.
Sec. 237. Reimbursement for federally qualified health centers providing services under MA plans.
Sec. 238. Institute of Medicine evaluation and report on health care performance measures.

Subtitle E—Comparative Cost Adjustment (CCA) Program

Sec. 241. Comparative Cost Adjustment (CCA) program.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Sec. 301. Medicare secondary payor (MSP) provisions.
Sec. 302. Payment for durable medical equipment; competitive acquisition of certain items and services.
Sec. 303. Payment reform for covered outpatient drugs and biologicals.
Sec. 304. Extension of application of payment reform for covered outpatient drugs and biologicals to other physician specialties.
Sec. 305. Payment for inhalation drugs.
Sec. 306. Demonstration project for use of recovery audit contractors.
Sec. 307. Pilot program for national and State background checks on direct patient access employees of long-term care facilities or providers.

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.
Sec. 402. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
Sec. 403. Adjustment to the medicare inpatient hospital prospective payment system wage index to revise the labor-related share of such index.
Sec. 404. More frequent update in weights used in hospital market basket.
Sec. 405. Improvements to critical access hospital program.
Sec. 406. Medicare inpatient hospital payment adjustment for low-volume hospitals.
Sec. 407. Treatment of missing cost reporting periods for sole community hospitals.
Sec. 408. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
Sec. 409. Rural hospice demonstration project.
Sec. 410. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
Sec. 410A. Rural community hospital demonstration program.

Subtitle B—Provisions Relating to Part B Only

Sec. 411. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under the prospective payment system for hospital outpatient department services.
Sec. 412. Establishment of floor on work geographic adjustment.
Sec. 413. Medicare incentive payment program improvements for physician scarcity.

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- Sec. 414. Payment for rural and urban ambulance services.
- Sec. 415. Providing appropriate coverage of rural air ambulance services.
- Sec. 416. Treatment of certain clinical diagnostic laboratory tests furnished to hospital outpatients in certain rural areas.
- Sec. 417. Extension of telemedicine demonstration project.
- Sec. 418. Report on demonstration project permitting skilled nursing facilities to be originating telehealth sites; authority to implement.

Subtitle C—Provisions Relating to Parts A and B

- Sec. 421. One-year increase for home health services furnished in a rural area.
- Sec. 422. Redistribution of unused resident positions.

Subtitle D—Other Provisions

- Sec. 431. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
- Sec. 432. Office of Rural Health Policy improvements.
- Sec. 433. MedPAC study on rural hospital payment adjustments.
- Sec. 434. Frontier extended stay clinic demonstration project.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 501. Revision of acute care hospital payment updates.
- Sec. 502. Revision of the indirect medical education (IME) adjustment percentage.
- Sec. 503. Recognition of new medical technologies under inpatient hospital prospective payment system.
- Sec. 504. Increase in Federal rate for hospitals in Puerto Rico.
- Sec. 505. Wage index adjustment reclassification reform.
- Sec. 506. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
- Sec. 507. Clarifications to certain exceptions to medicare limits on physician referrals.
- Sec. 508. One-time appeals process for hospital wage index classification.

Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
- Sec. 512. Coverage of hospice consultation services.
- Sec. 513. Study on portable diagnostic ultrasound services for beneficiaries in skilled nursing facilities.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
- Sec. 602. Treatment of physicians' services furnished in Alaska.
- Sec. 603. Inclusion of podiatrists, dentists, and optometrists under private contracting authority.
- Sec. 604. GAO study on access to physicians' services.
- Sec. 605. Collaborative demonstration-based review of physician practice expense geographic adjustment data.
- Sec. 606. MedPAC report on payment for physicians' services.

Subtitle B—Preventive Services

- Sec. 611. Coverage of an initial preventive physical examination.
- Sec. 612. Coverage of cardiovascular screening blood tests.
- Sec. 613. Coverage of diabetes screening tests.
- Sec. 614. Improved payment for certain mammography services.

Subtitle C—Other Provisions

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Limitation of application of functional equivalence standard.
- Sec. 623. Payment for renal dialysis services.
- Sec. 624. Two-year moratorium on therapy caps; provisions relating to reports.
- Sec. 625. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 626. Payment for services furnished in ambulatory surgical centers.
- Sec. 627. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 628. Payment for clinical diagnostic laboratory tests.
- Sec. 629. Indexing part B deductible to inflation.

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Sec. 630. Five-year authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

- Sec. 641. Demonstration project for coverage of certain prescription drugs and biologicals.
- Sec. 642. Extension of coverage of Intravenous Immune Globulin (IVIG) for the treatment of primary immune deficiency diseases in the home.
- Sec. 643. MedPAC study of coverage of surgical first assisting services of certified registered nurse first assistants.
- Sec. 644. MedPAC study of payment for cardio-thoracic surgeons.
- Sec. 645. Studies relating to vision impairments.
- Sec. 646. Medicare health care quality demonstration programs.
- Sec. 647. MedPAC study on direct access to physical therapy services.
- Sec. 648. Demonstration project for consumer-directed chronic outpatient services.
- Sec. 649. Medicare care management performance demonstration.
- Sec. 650. GAO study and report on the propagation of concierge care.
- Sec. 651. Demonstration of coverage of chiropractic services under medicare.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. Demonstration project to clarify the definition of homebound.
- Sec. 703. Demonstration project for medical adult day care services.
- Sec. 704. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.
- Sec. 705. MedPAC study on medicare margins of home health agencies.
- Sec. 706. Coverage of religious nonmedical health care institution services furnished in the home.

Subtitle B—Graduate Medical Education

- Sec. 711. Extension of update limitation on high cost programs.
- Sec. 712. Exception to initial residency period for geriatric residency or fellowship programs.
- Sec. 713. Treatment of volunteer supervision.

Subtitle C—Chronic Care Improvement

- Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
- Sec. 722. Medicare Advantage quality improvement programs.
- Sec. 723. Chronically ill medicare beneficiary research, data, demonstration strategy.

Subtitle D—Other Provisions

- Sec. 731. Improvements in national and local coverage determination process to respond to changes in technology.
- Sec. 732. Extension of treatment of certain physician pathology services under medicare.
- Sec. 733. Payment for pancreatic islet cell investigational transplants for medicare beneficiaries in clinical trials.
- Sec. 734. Restoration of medicare trust funds.
- Sec. 735. Modifications to Medicare Payment Advisory Commission (MedPAC).
- Sec. 736. Technical amendments.

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

- Sec. 801. Inclusion in annual report of medicare trustees of information on status of medicare trust funds.
- Sec. 802. Presidential submission of legislation.
- Sec. 803. Procedures in the House of Representatives.
- Sec. 804. Procedures in the Senate.

Subtitle B—Income-Related Reduction in Part B Premium Subsidy

- Sec. 811. Income-related reduction in part B premium subsidy.

TITLE IX—ADMINISTRATIVE IMPROVEMENTS, REGULATORY REDUCTION, AND CONTRACTING REFORM

- Sec. 900. Administrative improvements within the Centers for Medicare & Medicaid Services (CMS).

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(2) ESTABLISHMENT OF CLINICAL CONDITIONS OF COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(1) (42 U.S.C. 1395m(a)(1)) is amended by adding at the end the following new subparagraph:

“(E) CLINICAL CONDITIONS FOR COVERAGE.—

“(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

“(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

“(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

Effective date.

“(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

“(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.”.

(b) COMPETITIVE ACQUISITION.—

(1) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3) is amended to read as follows:

“COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

“SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

Contracts.

“(1) IMPLEMENTATION OF PROGRAMS.—

“(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

“(B) PHASED-IN IMPLEMENTATION.—The programs—

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“(i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in—

“(I) 10 of the largest metropolitan statistical areas in 2007;

“(II) 80 of the largest metropolitan statistical areas in 2009; and

“(III) additional areas after 2009; and

“(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

“(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

“(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

“(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

“(B) OTHER EQUIPMENT AND SUPPLIES.—Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

“(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

“(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

“(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

“(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

“(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT AND OXYGEN.—In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall

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provide for appropriate servicing and replacement, as required under section 1834(a).

“(5) PHYSICIAN AUTHORIZATION.—

“(A) IN GENERAL.—With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

“(B) NO EFFECT ON PAYMENT AMOUNT.—A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

“(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s), as appropriate.

“(b) PROGRAM REQUIREMENTS.—

“(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

“(2) CONDITIONS FOR AWARDING CONTRACT.—

“(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

“(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

“(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

“(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

“(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

“(B) TIMELY IMPLEMENTATION OF PROGRAM.—Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

“(3) CONTENTS OF CONTRACT.—

“(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

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“(B) TERM OF CONTRACTS.—The Secretary shall recompute contracts under this section not less often than once every 3 years.

“(4) LIMIT ON NUMBER OF CONTRACTORS.—

“(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

“(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

“(5) PAYMENT.—

“(A) IN GENERAL.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

“(B) REDUCED BENEFICIARY COST-SHARING.—

“(i) APPLICATION OF COINSURANCE.—Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

“(ii) APPLICATION OF DEDUCTIBLE.—Before applying clause (i), the individual shall be required to meet the deductible described in section 1833(b).

“(C) PAYMENT ON ASSIGNMENT-RELATED BASIS.—Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

“(D) CONSTRUCTION.—Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

“(6) PARTICIPATING CONTRACTORS.—

“(A) IN GENERAL.—Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

“(i) the contractor has submitted a bid for such items and services under this section; and

“(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

“(B) BID DEFINED.—In this section, the term ‘bid’ means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

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“(C) RULES FOR MERGERS AND ACQUISITIONS.—In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

“(D) PROTECTION OF SMALL SUPPLIERS.—In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

“(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

“(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES.—The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

“(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION.—The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

“(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

“(A) the establishment of payment amounts under paragraph (5);

“(B) the awarding of contracts under this section;

“(C) the designation of competitive acquisition areas under subsection (a)(1)(A);

“(D) the phased-in implementation under subsection (a)(1)(B);

“(E) the selection of items and services for competitive acquisition under subsection (a)(2); or

“(F) the bidding structure and number of contractors selected under this section.

“(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

“(1) ESTABLISHMENT.—The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the ‘Committee’).

“(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

“(3) DUTIES.—

“(A) ADVICE.—The Committee shall provide advice to the Secretary with respect to the following functions:

“(i) The implementation of the program under this section.

“(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

“(iii) The establishment of requirements for collection of data for the efficient management of the program.

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“(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.

“(v) The establishment of quality standards under section 1834(a)(20).

“(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

“(4) INAPPLICABILITY OF FACCA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

“(5) TERMINATION.—The Committee shall terminate on December 31, 2009.

“(d) REPORT.—Not later than July 1, 2009, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals. Deadline.

“(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

“(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

“(A) for which payment would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1834(d)(1) (relating to colorectal cancer screening tests); and

“(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

“(2) TERMS AND CONDITIONS.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

“(B) APPLICATION OF CLIA QUALITY STANDARDS.—The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

“(3) REPORT.—The Secretary shall submit to Congress— Deadline.

“(A) an initial report on the project not later than December 31, 2005; and

“(B) such progress and final reports on the project after such date as the Secretary determines appropriate.”.

(2) CONFORMING AMENDMENTS.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking “and (U)” and inserting “(U)”;

(B) by inserting before the semicolon at the end the following: “, and (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts

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paid shall be the amounts described in section 1847(b)(5)”;
and

(C) in clause (D)—

(i) by striking “or (ii)” and inserting “(ii)”; and

(ii) by adding at the end the following: “or (iii)

on the basis of a rate established under a demonstra-
tion project under section 1847(e), the amount paid
shall be equal to 100 percent of such rate,”.

42 USC 1395w–3
note.

(3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION
ON SUPPLIERS.—

(A) STUDY.—The Comptroller General of the United
States shall conduct a study on the impact of competitive
acquisition of durable medical equipment under section
1847 of the Social Security Act, as amended by paragraph
(1), on suppliers and manufacturers of such equipment
and on patients. Such study shall specifically examine the
impact of such competitive acquisition on access to, and
quality of, such equipment and service related to such
equipment.

Deadline.

(B) REPORT.—Not later than January 1, 2009, the
Comptroller General shall submit to Congress a report
on the study conducted under subparagraph (A) and shall
include in the report such recommendations as the Comp-
troller General determines appropriate.

(c) TRANSITIONAL FREEZE.—

(1) DME.—

(A) IN GENERAL.—Section 1834(a)(14) (42 U.S.C.
1395m(a)(14)) is amended—

(i) in subparagraph (E), by striking “and” at the
end;

(ii) in subparagraph (F)—

(I) by striking “a subsequent year” and
inserting “2003”; and

(II) by striking “the previous year.” and
inserting “2002;”; and

(iii) by adding at the end the following new sub-
paragraphs:

“(G) for 2004 through 2006—

“(i) subject to clause (ii), in the case of class III
medical devices described in section 513(a)(1)(C) of the
Federal Food, Drug, and Cosmetic Act (21 U.S.C.
360(c)(1)(C)), the percentage increase described in
subparagraph (B) for the year involved; and

“(ii) in the case of covered items not described
in clause (i), 0 percentage points;

“(H) for 2007—

“(i) subject to clause (ii), in the case of class III
medical devices described in section 513(a)(1)(C) of the
Federal Food, Drug, and Cosmetic Act (21 U.S.C.
360(c)(1)(C)), the percentage change determined by the
Secretary to be appropriate taking into account rec-
ommendations contained in the report of the Comp-
troller General of the United States under section
302(c)(1)(B) of the Medicare Prescription Drug,
Improvement, and Modernization Act of 2003; and

“(ii) in the case of covered items not described
in clause (i), 0 percentage points; and

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“(I) for 2008—

“(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

“(ii) in the case of covered items not described in clause (i), 0 percentage points; and

“(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.”.

(B) GAO REPORT ON CLASS III MEDICAL DEVICES.—Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary, a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) furnished to medicare beneficiaries during 2007 and 2008.

Deadline.
42 USC 1395m
note.

(2) PAYMENT RULE FOR SPECIFIED ITEMS.—Section 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

“(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

“(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

“(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

“(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled ‘Median FEHP Price’ in the table entitled ‘SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS’ included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

“(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

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“(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.”.

(3) PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—Section 1834(h)(4)(A) (42 U.S.C. 1395m(h)(4)(A)) is amended—

- (A) in clause (vii), by striking “and” at the end;
- (B) in clause (viii), by striking “a subsequent year” and inserting “2003”; and
- (C) by adding at the end the following new clauses:
 - “(ix) for 2004, 2005, and 2006, 0 percent; and
 - “(x) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;”.

(d) CONFORMING AMENDMENTS.—

(1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

- (A) in paragraph (1)(B), by striking “The payment basis” and inserting “Subject to subparagraph (F)(i), the payment basis”;
- (B) in paragraph (1)(C), by striking “This subsection” and inserting “Subject to subparagraph (F)(ii), this subsection”;
- (C) by adding at the end of paragraph (1) the following new subparagraph:

“(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

“(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

“(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.”; and

(D) in paragraph (10)(B), by inserting “in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F)” after “under this subsection”.

(2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—

- (A) in paragraph (1)(B), by striking “and (E)” and inserting “, (E), and (H)(i)”;

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(B) in paragraph (1)(D), by striking “This subsection” and inserting “Subject to subparagraph (H)(ii), this subsection”; and

(C) by adding at the end of paragraph (1) the following new subparagraph:

“(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under such section—

“(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

“(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.”.

(3) OTHER ITEMS AND SERVICES; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1842(s) (42 U.S.C. 1395u(s)) is amended—

(A) in the first sentence of paragraph (1), by striking “The Secretary” and inserting “Subject to paragraph (3), the Secretary”; and

(B) by adding at the end the following new paragraph:

“(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

“(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

“(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.”.

(e) REPORT ON ACTIVITIES OF SUPPLIERS.—The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2009, the Inspector General shall submit to Congress a report on such study.

42 USC 1395w-3 note.

Deadline.

SEC. 303. PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

122 STAT. 2494

PUBLIC LAW 110-275—JULY 15, 2008

Public Law 110-275
110th Congress

An Act

July 15, 2008
[H.R. 6331]

To amend titles XVIII and XIX of the Social Security Act to extend expiring provisions under the Medicare Program, to improve beneficiary access to preventive and mental health services, to enhance low-income benefit programs, and to maintain access to care in rural areas, including pharmacy access, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Medicare
Improvements
for Patients and
Providers Act of
2008.
Inter-
governmental
relations.
42 USC 1305
note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Medicare Improvements for Patients and Providers Act of 2008”.

(b) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MEDICARE

Subtitle A—Beneficiary Improvements

PART I—PREVENTION, MENTAL HEALTH, AND MARKETING

- Sec. 101. Improvements to coverage of preventive services.
- Sec. 102. Elimination of discriminatory copayment rates for Medicare outpatient psychiatric services.
- Sec. 103. Prohibitions and limitations on certain sales and marketing activities under Medicare Advantage plans and prescription drug plans.
- Sec. 104. Improvements to the Medigap program.

PART II—LOW-INCOME PROGRAMS

- Sec. 111. Extension of qualifying individual (QI) program.
- Sec. 112. Application of full LIS subsidy assets test under Medicare Savings Program.
- Sec. 113. Eliminating barriers to enrollment.
- Sec. 114. Elimination of Medicare part D late enrollment penalties paid by subsidy eligible individuals.
- Sec. 115. Eliminating application of estate recovery.
- Sec. 116. Exemptions from income and resources for determination of eligibility for low-income subsidy.
- Sec. 117. Judicial review of decisions of the Commissioner of Social Security under the Medicare part D low-income subsidy program.
- Sec. 118. Translation of model form.
- Sec. 119. Medicare enrollment assistance.

Subtitle B—Provisions Relating to Part A

- Sec. 121. Expansion and extension of the Medicare Rural Hospital Flexibility Program.
- Sec. 122. Rebasing for sole community hospitals.
- Sec. 123. Demonstration project on community health integration models in certain rural counties.
- Sec. 124. Extension of the reclassification of certain hospitals.
- Sec. 125. Revocation of unique deeming authority of the Joint Commission.

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Subtitle C—Provisions Relating to Part B

PART I—PHYSICIANS’ SERVICES

- Sec. 131. Physician payment, efficiency, and quality improvements.
- Sec. 132. Incentives for electronic prescribing.
- Sec. 133. Expanding access to primary care services.
- Sec. 134. Extension of floor on Medicare work geographic adjustment under the Medicare physician fee schedule.
- Sec. 135. Imaging provisions.
- Sec. 136. Extension of treatment of certain physician pathology services under Medicare.
- Sec. 137. Accommodation of physicians ordered to active duty in the Armed Services.
- Sec. 138. Adjustment for Medicare mental health services.
- Sec. 139. Improvements for Medicare anesthesia teaching programs.

PART II—OTHER PAYMENT AND COVERAGE IMPROVEMENTS

- Sec. 141. Extension of exceptions process for Medicare therapy caps.
- Sec. 142. Extension of payment rule for brachytherapy and therapeutic radiopharmaceuticals.
- Sec. 143. Speech-language pathology services.
- Sec. 144. Payment and coverage improvements for patients with chronic obstructive pulmonary disease and other conditions.
- Sec. 145. Clinical laboratory tests.
- Sec. 146. Improved access to ambulance services.
- Sec. 147. Extension and expansion of the Medicare hold harmless provision under the prospective payment system for hospital outpatient department (HOPD) services for certain hospitals.
- Sec. 148. Clarification of payment for clinical laboratory tests furnished by critical access hospitals.
- Sec. 149. Adding certain entities as originating sites for payment of telehealth services.
- Sec. 150. MedPAC study and report on improving chronic care demonstration programs.
- Sec. 151. Increase of FQHC payment limits.
- Sec. 152. Kidney disease education and awareness provisions.
- Sec. 153. Renal dialysis provisions.
- Sec. 154. Delay in and reform of Medicare DMEPOS competitive acquisition program.

Subtitle D—Provisions Relating to Part C

- Sec. 161. Phase-out of indirect medical education (IME).
- Sec. 162. Revisions to requirements for Medicare Advantage private fee-for-service plans.
- Sec. 163. Revisions to quality improvement programs.
- Sec. 164. Revisions relating to specialized Medicare Advantage plans for special needs individuals.
- Sec. 165. Limitation on out-of-pocket costs for dual eligibles and qualified medicare beneficiaries enrolled in a specialized Medicare Advantage plan for special needs individuals.
- Sec. 166. Adjustment to the Medicare Advantage stabilization fund.
- Sec. 167. Access to Medicare reasonable cost contract plans.
- Sec. 168. MedPAC study and report on quality measures.
- Sec. 169. MedPAC study and report on Medicare Advantage payments.

Subtitle E—Provisions Relating to Part D

PART I—IMPROVING PHARMACY ACCESS

- Sec. 171. Prompt payment by prescription drug plans and MA–PD plans under part D.
- Sec. 172. Submission of claims by pharmacies located in or contracting with long-term care facilities.
- Sec. 173. Regular update of prescription drug pricing standard.

PART II—OTHER PROVISIONS

- Sec. 175. Inclusion of barbiturates and benzodiazepines as covered part D drugs.
- Sec. 176. Formulary requirements with respect to certain categories or classes of drugs.

Subtitle F—Other Provisions

- Sec. 181. Use of part D data.

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(2) The mode of administering such agents, including information on the proportion of individuals receiving such agents intravenously as compared to subcutaneously.

(3) An analysis of the payment adjustment under subparagraph (D)(iii) of such subsection (b)(14), including an examination of the extent to which costs incurred by rural, low-volume providers and facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other providers and facilities in furnishing such services, and a recommendation regarding the appropriateness of such adjustment.

(4) The changes, if any, in utilization rates of drugs and biologicals that the Secretary identifies under subparagraph (B)(iii) of such subsection (b)(14), and any oral equivalent or oral substitutable forms of such drugs and biologicals or of drugs and biologicals described in clause (ii), that have occurred after implementation of the payment system under such subsection (b)(14).

(5) Any other information or recommendations for legislative and administrative actions determined appropriate by the Comptroller General.

SEC. 154. DELAY IN AND REFORM OF MEDICARE DMEPOS COMPETITIVE ACQUISITION PROGRAM.

(a) TEMPORARY DELAY AND REFORM.—

(1) IN GENERAL.—Section 1847(a)(1) of the Social Security Act (42 U.S.C. 1395w–3(a)(1)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (B)(i), in the matter before subclause (I), by inserting “consistent with subparagraph (D)” after “in a manner”;

(ii) in subparagraph (B)(i)(II), by striking “80” and “in 2009” and inserting “an additional 70” and “in 2011”, respectively;

(iii) in subparagraph (B)(i)(III), by striking “after 2009” and inserting “after 2011 (or, in the case of national mail order for items and services, after 2010)”; and

(iv) by adding at the end the following new subparagraphs:

“(D) CHANGES IN COMPETITIVE ACQUISITION PROGRAMS.—

“(i) ROUND 1 OF COMPETITIVE ACQUISITION PROGRAM.—Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

“(I) the contracts awarded under this section before the date of the enactment of this subparagraph are terminated, no payment shall be made under this title on or after the date of the enactment of this subparagraph based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1841;

Contracts.

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“(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

“(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

Puerto Rico.

“(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

“(ii) ROUND 2 OF COMPETITIVE ACQUISITION PROGRAM.—In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

“(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008; and

“(II) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

“(iii) EXCLUSION OF CERTAIN AREAS IN SUBSEQUENT ROUNDS OF COMPETITIVE ACQUISITION PROGRAMS.—In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

“(I) Rural areas.

“(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

“(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

“(E) VERIFICATION BY OIG.—The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

“(F) SUPPLIER FEEDBACK ON MISSING FINANCIAL DOCUMENTATION.—

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Deadlines.

“(i) IN GENERAL.—In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

“(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

“(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

“(ii) COVERED DOCUMENT REVIEW DATE.—The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

“(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

“(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

“(iii) LIMITATIONS OF PROCESS.—The process provided under this subparagraph—

“(I) applies only to the timely submission of covered documents;

“(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

“(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

“(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

“(iv) COVERED DOCUMENT DEFINED.—In this subparagraph, the term ‘covered document’ means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.”; and

(B) in paragraph (2)(A), by inserting before the period at the end the following: “and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related

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accessories when furnished in connection with such wheelchairs”.

(2) BUDGET NEUTRAL OFFSET.—

(A) IN GENERAL.—Section 1834(a)(14) of such Act (42 U.S.C. 1395m(a)(14)) is amended—

(i) by striking “and” at the end of subparagraphs (H) and (I);

(ii) by redesignating subparagraph (J) as subparagraph (M); and

(iii) by inserting after subparagraph (I) the following new subparagraphs:

“(J) for 2009—

“(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

“(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

“(K) for 2010, 2011, 2012, and 2013, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year;

“(L) for 2014—

“(i) in the case of items and services described in subparagraph (J)(i) for which a payment adjustment has not been made under subsection (a)(1)(F)(ii) in any previous year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013, plus 2.0 percentage points; or

“(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013; and”.

(B) CONFORMING TREATMENT FOR CERTAIN ITEMS AND SERVICES.—The second sentence of section 1842(s)(1) of such Act (42 U.S.C. 1395u(s)(1)) is amended by striking “except that” and all that follows and inserting the following: “except that for items and services described in paragraph (2)(D)—

“(A) for 2009 section 1834(a)(14)(J)(i) shall apply under this paragraph instead of the percentage increase otherwise applicable; and

“(B) for 2014, if subparagraph (A) is applied to the items and services and there has not been a payment adjustment under paragraph (3)(B) for the items and services for any previous year, the percentage increase computed under section 1834(a)(14)(L)(i) shall apply instead of the percentage increase otherwise applicable.”.

Applicability.

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(3) CONFORMING DELAY.—Subsections (a)(1)(F) and (h)(1)(H) of section 1834 of the Social Security Act (42 U.S.C. 1395m) are each amended by striking “January 1, 2009” and inserting “January 1, 2011”.

(4) CONSIDERATIONS IN APPLICATION.—Section 1834 of such Act (42 U.S.C. 1395m) is amended—

(A) in subsection (a)(1)—

(i) in subparagraph (F), by inserting “subject to subparagraph (G),” before “that are included”; and

(ii) by adding at the end the following new subparagraph:

“(G) USE OF INFORMATION ON COMPETITIVE BID RATES.—

Regulations.

The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.”; and

(B) in subsection (h)(1)(H), by inserting “subject to subsection (a)(1)(G),” before “that are included”.

(b) QUALITY STANDARDS.—

(1) APPLICATION OF ACCREDITATION REQUIREMENT.—

(A) IN GENERAL.—Section 1834(a)(20) of the Social Security Act (42 U.S.C. 1395m(a)(20)) is amended—

(i) in subparagraph (E), by inserting “including subparagraph (F),” after “under this paragraph,”; and

(ii) by adding at the end the following new subparagraph:

“(F) APPLICATION OF ACCREDITATION REQUIREMENT.—

Effective date.

In implementing quality standards under this paragraph—

“(i) subject to clause (ii), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards; and

“(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

“(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

“(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality

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requirements apply to such professionals and persons with respect to the furnishing of such items and services.”.

(B) CONSTRUCTION.—Section 1834(a)(20)(F)(ii) of the Social Security Act, as added by subparagraph (A), shall not be construed as preventing the Secretary of Health and Human Services from implementing the first round of competition under section 1847 of such Act on a timely basis. 42 USC 1395m note.

(2) DISCLOSURE OF SUBCONTRACTORS UNDER COMPETITIVE ACQUISITION PROGRAM.—Section 1847(b)(3) of such Act (42 U.S.C. 1395w-3(b)(3)) is amended by adding at the end the following new subparagraph:

“(C) DISCLOSURE OF SUBCONTRACTORS.—

“(i) INITIAL DISCLOSURE.—Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on— Deadline.

“(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

“(II) whether each such subcontractor meets the requirement of section 1834(a)(20)(F)(i), if applicable to such subcontractor.

“(ii) SUBSEQUENT DISCLOSURE.—Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).”.

(3) COMPETITIVE ACQUISITION OMBUDSMAN.—Such section is further amended by adding at the end the following new subsection:

“(f) COMPETITIVE ACQUISITION OMBUDSMAN.—The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1808(c). The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1808(c)(2)(C).” Establishment.

(c) CHANGE IN REPORTS AND DEADLINES.—

(1) GAO REPORT.—Section 302(b)(3) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is amended—

(A) in subparagraph (A)—

(i) by inserting “and as amended by section 2 of the Medicare DMEPOS Competitive Acquisition Reform Act of 2008” after “as amended by paragraph (1)”; and 42 USC 1395w-3 note.

(ii) by inserting before the period at the end the following: “and the topics specified in subparagraph (C)”;

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(B) in subparagraph (B), by striking “Not later than January 1, 2009,” and inserting “Not later than 1 year after the first date that payments are made under section 1847 of the Social Security Act,”; and

(C) by adding at the end the following new subparagraph:

“(C) TOPICS.—The topics specified in this subparagraph, for the study under subparagraph (A) concerning the competitive acquisition program, are the following:

“(i) Beneficiary access to items and services under the program, including the impact on such access of awarding contracts to bidders that—

“(I) did not have a physical presence in an area where they received a contract; or

“(II) had no previous experience providing the product category they were contracted to provide.

“(ii) Beneficiary satisfaction with the program and cost savings to beneficiaries under the program.

“(iii) Costs to suppliers of participating in the program and recommendations about ways to reduce those costs without compromising quality standards or savings to the Medicare program.

“(iv) Impact of the program on small business suppliers.

“(v) Analysis of the impact on utilization of different items and services paid within the same Healthcare Common Procedure Coding System (HCPCS) code.

“(vi) Costs to the Centers for Medicare & Medicaid Services, including payments made to contractors, for administering the program compared with administration of a fee schedule, in comparison with the relative savings of the program.

“(vii) Impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how such supplies are furnished.

“(viii) Such other topics as the Comptroller General determines to be appropriate.”.

(2) DELAY IN OTHER DEADLINES.—

(A) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—Section 1847(c)(5) of the Social Security Act (42 U.S.C. 1395w-3(c)(5)) is amended by striking “December 31, 2009” and inserting “December 31, 2011”.

(B) SECRETARIAL REPORT.—Section 1847(d) of such Act (42 U.S.C. 1395w-3(d)) is amended by striking “July 1, 2009” and inserting “July 1, 2011”.

(C) IG REPORT.—Section 302(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is amended by striking “July 1, 2009” and inserting “July 1, 2011”.

(3) EVALUATION OF CERTAIN CODE.—The Secretary of Health and Human Services shall evaluate the existing Health Care Common Procedure Coding System (HCPCS) codes for negative pressure wound therapy to ensure accurate reporting and billing for items and services under such codes. In carrying out such evaluation, the Secretary shall use an existing process,

42 USC 1395w-3 note.

42 USC 1395m note.

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administered by the Durable Medical Equipment Medicare Administrative Contractors, for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such process.

(d) OTHER PROVISIONS.—

(1) EXEMPTION FROM COMPETITIVE ACQUISITION FOR CERTAIN OFF-THE-SHELF ORTHOTICS.—Section 1847(a) of the Social Security Act (42 U.S.C. 1395w-3(a)) is amended by adding at the end the following new paragraph:

“(7) EXEMPTION FROM COMPETITIVE ACQUISITION.—The programs under this section shall not apply to the following:

“(A) CERTAIN OFF-THE-SHELF ORTHOTICS.—Items and services described in paragraph (2)(C) if furnished—

“(i) by a physician or other practitioner (as defined by the Secretary) to the physician’s or practitioner’s own patients as part of the physician’s or practitioner’s professional service; or

“(ii) by a hospital to the hospital’s own patients during an admission or on the date of discharge.

“(B) CERTAIN DURABLE MEDICAL EQUIPMENT.—Those items and services described in paragraph (2)(A)—

“(i) that are furnished by a hospital to the hospital’s own patients during an admission or on the date of discharge; and

“(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician’s own patients as part of the physician’s professional service.”.

(2) CORRECTION IN FACE-TO-FACE EXAMINATION REQUIREMENT.—Section 1834(a)(1)(E)(ii) of such Act (42 U.S.C. 1395m(a)(1)(E)(ii)) is amended by striking “1861(r)(1)” and inserting “1861(r)”.

(3) SPECIAL RULE IN CASE OF NATIONAL MAIL-ORDER COMPETITION FOR DIABETIC TESTING STRIPS.—Section 1847(b) of such Act (42 U.S.C. 1395w-3(b)) is amended—

(A) by redesignating paragraph (10) as paragraph (11);

and

(B) by inserting after paragraph (9) the following new paragraph:

“(10) SPECIAL RULE IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.—

“(A) IN GENERAL.—With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

“(B) STUDY OF TYPES OF TESTING STRIP PRODUCTS.—Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume

Deadline.

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Reports.

that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquisition program described in subparagraph (A).”

(4) OTHER CONFORMING AMENDMENTS.—Section 1847(b)(11) of such Act, as redesignated by paragraph (3), is amended—

(A) in subparagraph (C), by inserting “and the identification of areas under subsection (a)(1)(D)(iii)” after “(a)(1)(A)”;

(B) in subparagraph (D), by inserting “and implementation of subsection (a)(1)(D)” after “(a)(1)(B)”;

(C) in subparagraph (E), by striking “or” at the end;

(D) in subparagraph (F), by striking the period at the end and inserting “; or”; and

(E) by adding at the end the following new subparagraph:

“(G) the implementation of the special rule described in paragraph (10).”

(5) FUNDING FOR IMPLEMENTATION.—In addition to funds otherwise available, for purposes of implementing the provisions of, and amendments made by, this section, other than the amendment made by subsection (c)(1) and other than section 1847(a)(1)(E) of the Social Security Act, the Secretary of Health and Human Services shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of \$20,000,000 for fiscal year 2008, and \$25,000,000 for each of fiscal years 2009 through 2012. Amounts transferred under this paragraph for a fiscal year shall be available until expended.

42 USC 1395m
note.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect as of June 30, 2008.

Subtitle D—Provisions Relating to Part C

SEC. 161. PHASE-OUT OF INDIRECT MEDICAL EDUCATION (IME).

(a) IN GENERAL.—Section 1853(k) of the Social Security Act (42 U.S.C. 1395w–23(k)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by striking “paragraph (2)” and inserting “paragraphs (2) and (4)”;

(2) by adding at the end the following new paragraph:

“(4) PHASE-OUT OF THE INDIRECT COSTS OF MEDICAL EDUCATION FROM CAPITATION RATES.—

“(A) IN GENERAL.—After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2010), the Secretary shall adjust such applicable amount to exclude from such applicable amount the phase-in percentage (as defined in subparagraph (B)(i)) for the year of the Secretary’s estimate of the standardized costs for payments under section 1886(d)(5)(B) in the area for

tem of the Health Care Financing Administration, the provisions of section 1870(c) of the Social Security Act [subsec. (c) of this section] shall apply, without the need for affirmative action by such a physician or individual, so as to prevent any recoupment, or other decrease in subsequent payments, to the physician or individual. The previous sentence shall apply to claims for items and services which were reopened by carriers on or after July 31, 1987.”

§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term “regulations” means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final reg-

ulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

(e)¹ Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

- (i) such retroactive application is necessary to comply with statutory requirements; or
- (ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to non-compliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1395zz(g) of this title) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI of this chapter insofar as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely

the result of a clerical or technical operational error.

(f) Report on areas of inconsistency or conflict

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) information from individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

(Aug. 14, 1935, ch. 531, title XVIII, § 1871, as added Pub. L. 89-97, title I, § 102(a) July 30, 1965, 79 Stat. 331; amended Pub. L. 99-509, title IX, § 9321(e)(1), Oct. 21, 1986, 100 Stat. 2017; Pub. L. 100-203, title IV, § 4035(b), (c), Dec. 22, 1987, 101 Stat. 1330-78; Pub. L. 108-173, title IX, §§ 902(a)(1), (b)(1), 903(a)(1), (b)(1), (c)(1), 904(b), Dec. 8, 2003, 117 Stat. 2375-2377.)

REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsec. (f)(2)(A), are classified to sections 1395c et seq. and 1395j et seq., respectively, of this title.

AMENDMENTS

2003—Subsec. (a)(3). Pub. L. 108-173, § 902(a)(1), added par. (3).

Subsec. (a)(4). Pub. L. 108-173, § 902(b)(1), added par. (4).

Subsec. (e). Pub. L. 108-173, § 903(a)(1), added subsec. (e).

Subsec. (e)(1)(B), (C). Pub. L. 108-173, § 903(b)(1), added subpars. (B) and (C).

Subsec. (e)(2). Pub. L. 108-173, § 903(c)(1), added par. (2).

Subsec. (f). Pub. L. 108-173, § 904(b), added subsec. (f). 1987—Subsec. (a). Pub. L. 100-203, § 4035(b), designated existing provisions as par. (1) and added par. (2).

Subsec. (c). Pub. L. 100-203, § 4035(c), added subsec. (c). 1986—Pub. L. 99-509 designated existing provisions as subsec. (a) and added subsec. (b).

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108-173, title IX, § 902(a)(2), Dec. 8, 2003, 117 Stat. 2375, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003]. The Secretary [of Health and Human Services] shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations."

Pub. L. 108-173, title IX, § 902(b)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to final regulations published on or after the date of the enactment of this Act [Dec. 8, 2003]."

¹ So in original. No subsec. (d) has been enacted.

Pub. L. 108-173, title IX, §903(a)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to substantive changes issued on or after the date of the enactment of this Act [Dec. 8, 2003].”

Pub. L. 108-173, title IX, §903(b)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to compliance actions undertaken on or after the date of the enactment of this Act [Dec. 8, 2003].”

Pub. L. 108-173, title IX, §903(c)(2), Dec. 8, 2003, 117 Stat. 2377, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003] and shall only apply to a penalty or interest imposed with respect to guidance provided on or after July 24, 2003.”

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100-203 effective Dec. 22, 1987, and applicable to budgets for fiscal years beginning with fiscal year 1989, see section 4035(a)(3) of Pub. L. 100-203, set out as a note under section 1395h of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Section 9321(e)(3)(A) of Pub. L. 99-509 provided that: “The amendments made by paragraph (1) [amending this section] shall apply to notices of proposed rule-making issued after the date of the enactment of this Act [Oct. 21, 1986].”

REGULATIONS

Pub. L. 101-508, title IV, §4207(j), formerly §4027(j), Nov. 5, 1990, 104 Stat. 1388-124, as renumbered and amended by Pub. L. 103-432, title I, §160(d)(4), (12), Oct. 31, 1994, 108 Stat. 4444, provided that: “The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subtitle [subtitle A (§§4000-4361) of title IV of Pub. L. 101-508, see Tables for classification] and the amendments made by this subtitle.”

Section 4039(g) of title IV of Pub. L. 100-203 provided that: “The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subtitle and the amendments made by this subtitle [subtitle A (§§4001-4097) of title IV of Pub. L. 100-203, see Tables for classification].”

GAO STUDY ON ADVISORY OPINION AUTHORITY

Pub. L. 108-173, title IX, §904(a), Dec. 8, 2003, 117 Stat. 2377, provided that:

“(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary [of Health and Human Services] authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act [this subchapter]. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

“(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003].”

§ 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect

to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(Aug. 14, 1935, ch. 531, title XVIII, §1872, as added Pub. L. 89-97, title I, §102(a), July 30, 1965, 79 Stat. 332; amended Pub. L. 92-603, title II, §242(a), Oct. 30, 1972, 86 Stat. 1419; Pub. L. 98-369, div. B, title III, §2354(b)(36), July 18, 1984, 98 Stat. 1102; Pub. L. 103-296, title I, §108(c)(4), Aug. 15, 1994, 108 Stat. 1485.)

AMENDMENTS

1994—Pub. L. 103-296 inserted before period at end “, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively”.

1984—Pub. L. 98-369 struck out the comma after “406” and struck out reference to subsec. (f) of section 405 of this title.

1972—Pub. L. 92-603 struck out reference to provisions of section 408 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103-296, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98-369, set out as a note under section 1320a-1 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-603 not applicable to any acts, statements, or representations made or committed prior to Oct. 30, 1972, see section 242(d) of Pub. L. 92-603, set out as an Effective Date note under section 1320a-7b of this title.

§ 1395jj. Designation of organization or publication by name

Designation in this subchapter, by name, of any nongovernmental organization or publication shall not be affected by change of name of such organization or publication, and shall apply to any successor organization or publication which the Secretary finds serves the purpose for which such designation is made.

(Aug. 14, 1935, ch. 531, title XVIII, §1873, as added Pub. L. 89-97, title I, §102(a), July 30, 1965, 79 Stat. 332.)

§ 1395kk. Administration of insurance programs

(a) Functions of Secretary; performance directly or by contract

Except as otherwise provided in this subchapter and in the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], the insurance programs established by this subchapter shall be administered by the Secretary. The Secretary may perform any of his functions under this subchapter directly, or by contract providing for

(m) Nothing in this section authorizes any agency to withhold from any individual any record, including transcripts, recordings, or minutes required by this section, which is otherwise accessible to such individual under section 552a of this title.

(Added Pub. L. 94-409, §3(a), Sept. 13, 1976, 90 Stat. 1241; amended Pub. L. 104-66, title III, §3002, Dec. 21, 1995, 109 Stat. 734.)

REFERENCES IN TEXT

Section 552(e) of this title, referred to in subsec. (a)(1), was redesignated section 552(f) of this title by section 1802(b) of Pub. L. 99-570.

180 days after the date of enactment of this section, referred to in subsec. (g), means 180 days after the date of enactment of Pub. L. 94-409, which was approved Sept. 13, 1976.

AMENDMENTS

1995—Subsec. (j). Pub. L. 104-66 amended subsec. (j) generally. Prior to amendment, subsec. (j) read as follows: “Each agency subject to the requirements of this section shall annually report to Congress regarding its compliance with such requirements, including a tabulation of the total number of agency meetings open to the public, the total number of meetings closed to the public, the reasons for closing such meetings, and a description of any litigation brought against the agency under this section, including any costs assessed against the agency in such litigation (whether or not paid by the agency).”

EFFECTIVE DATE

Section 6 of Pub. L. 94-409 provided that: “(a) Except as provided in subsection (b) of this section, the provisions of this Act [see Short Title note set out below] shall take effect 180 days after the date of its enactment [Sept. 13, 1976].

“(b) Subsection (g) of section 552b of title 5, United States Code, as added by section 3(a) of this Act, shall take effect upon enactment [Sept. 13, 1976].”

SHORT TITLE OF 1976 AMENDMENT

Section 1 of Pub. L. 94-409 provided: “That this Act [enacting this section, amending sections 551, 552, 556, and 557 of this title, section 10 of Pub. L. 92-463, set out in the Appendix to this title, and section 410 of Title 39, and enacting provisions set out as notes under this section] may be cited as the ‘Government in the Sunshine Act’.”

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103-7 (in which the report required by subsec. (j) of this section is listed on page 151), see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.

TERMINATION OF ADMINISTRATIVE CONFERENCE OF UNITED STATES

For termination of Administrative Conference of United States, see provision of title IV of Pub. L. 104-52, set out as a note preceding section 591 of this title.

DECLARATION OF POLICY AND STATEMENT OF PURPOSE

Section 2 of Pub. L. 94-409 provided that: “It is hereby declared to be the policy of the United States that the public is entitled to the fullest practicable information regarding the decisionmaking processes of the Federal Government. It is the purpose of this Act [see Short Title note set out above] to provide the public with such information while protecting the rights of individ-

uals and the ability of the Government to carry out its responsibilities.”

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

- (1) a military or foreign affairs function of the United States; or
- (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

- (1) a statement of the time, place, and nature of public rule making proceedings;
- (2) reference to the legal authority under which the rule is proposed; and
- (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

- (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
- (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

- (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
- (2) interpretative rules and statements of policy; or
- (3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 383.)

HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
.....	5 U.S.C. 1003.	June 11, 1946, ch. 324, §4, 60 Stat. 238.

In subsection (a)(1), the words “or naval” are omitted as included in “military”.

In subsection (b), the word “when” is substituted for “in any situation in which”.

In subsection (c), the words “for oral presentation” are substituted for “to present the same orally in any manner”. The words “sections 556 and 557 of this title apply instead of this subsection” are substituted for “the requirements of sections 1006 and 1007 of this title shall apply in place of the provisions of this subsection”.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

CODIFICATION

Section 553 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2245 of Title 7, Agriculture.

EXECUTIVE ORDER NO. 12044

Ex. Ord. No. 12044, Mar. 23, 1978, 43 F.R. 12661, as amended by Ex. Ord. No. 12221, June 27, 1980, 45 F.R. 44249, which related to the improvement of Federal regulations, was revoked by Ex. Ord. No. 12291, Feb. 17, 1981, 46 F.R. 13193, formerly set out as a note under section 601 of this title.

§ 554. Adjudications

(a) This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved—

- (1) a matter subject to a subsequent trial of the law and the facts de novo in a court;
- (2) the selection or tenure of an employee, except a¹ administrative law judge appointed under section 3105 of this title;
- (3) proceedings in which decisions rest solely on inspections, tests, or elections;
- (4) the conduct of military or foreign affairs functions;
- (5) cases in which an agency is acting as an agent for a court; or
- (6) the certification of worker representatives.

(b) Persons entitled to notice of an agency hearing shall be timely informed of—

- (1) the time, place, and nature of the hearing;
- (2) the legal authority and jurisdiction under which the hearing is to be held; and
- (3) the matters of fact and law asserted.

When private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law; and in other instances agencies may by rule require responsive pleading. In fixing the time and place for hearings, due regard shall be had for the convenience and necessity of the parties or their representatives.

(c) The agency shall give all interested parties opportunity for—

- (1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment when time, the nature of the proceeding, and the public interest permit; and
- (2) to the extent that the parties are unable so to determine a controversy by consent, hearing and decision on notice and in accordance with sections 556 and 557 of this title.

¹ So in original.

(d) The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not—

- (1) consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or
- (2) be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecuting functions for an agency.

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. This subsection does not apply—

- (A) in determining applications for initial licenses;
- (B) to proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; or
- (C) to the agency or a member or members of the body comprising the agency.

(e) The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 384; Pub. L. 95-251, § 2(a)(1), Mar. 27, 1978, 92 Stat. 183.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1004.	June 11, 1946, ch. 324, § 5, 60 Stat. 239.

In subsection (a)(2), the word “employee” is substituted for “officer or employee of the United States” in view of the definition of “employee” in section 2105.

In subsection (a)(4), the word “naval” is omitted as included in “military”.

In subsection (a)(5), the word “or” is substituted for “and” since the exception is applicable if any one of the factors are involved.

In subsection (a)(6), the word “worker” is substituted for “employee”, since the latter is defined in section 2105 as meaning Federal employees.

In subsection (b), the word “When” is substituted for “In instances in which”.

In subsection (c)(2), the comma after the word “hearing” is omitted to correct an editorial error.

In subsection (d), the words “The employee” and “such an employee” are substituted in the first two sentences for “The same officers” and “such officers” in view of the definition of “employee” in section 2105. The word “officer” is omitted in the third and fourth sentences as included in “employee” as defined in section 2105. The prohibition in the third and fourth sentences is restated in positive form. In paragraph (C) of the last sentence, the words “in any manner” are omitted as surplusage.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 414, and 424

[CMS-1270-P]

RIN 0938-AN14

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act (the Act). These programs would change the way that Medicare pays for these items under Part B of the Medicare program by utilizing bids submitted by DMEPOS suppliers to establish applicable payment amounts. We would phase in these programs over several years.

This proposed rule would also detail requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers that participate in the DMEPOS competitive bidding program. In addition, this rule proposes a new fee schedule for home dialysis supplies and equipment still paid on a reasonable charge basis. This proposed rule would also clarify our policy on the scope of the statutory eyeglass coverage exclusion. We are proposing to specify in regulations that the eyeglass exclusion encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision. Further, this proposed rule would implement a revised methodology for calculating fee schedule amounts for new DMEPOS items.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 30, 2006.

ADDRESSES: In commenting, please refer to file code CMS-1270-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1270-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1270-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Lorrie Ballantine, (410) 786-7543—

Overall implementation.

Joel Kaiser, (410) 786-4499—Overall implementation.

Michael Keane, (410) 786-4495—

Overall implementation.

Walter Rutemueller, (410) 786-5395—Overall implementation.

Linda Smith, (410) 786-5650—Quality Standards and Accreditation.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1270-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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1834(a)(20) of the Act. Section 1834(a)(20) instructs the Secretary to establish and implement quality standards for all DMEPOS suppliers in the Medicare program, not just for suppliers in the competitive bidding areas. All suppliers will have to meet these quality standards to be eligible to submit claims to the Medicare program, irrespective of the competitive bidding program. The quality standards are to be applied by recognized independent accreditation organizations designated by the Secretary under section 1834(a)(20)(B) of the Act. A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, we will suspend or terminate the supplier contract. The length of time for the grace period will be determined by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area. The length of time of the grace period will be specified in the RFB for each competitive bidding program. We solicit public comments on the length of time for the grace period.

Suppliers that received a valid accreditation before CMS-approved accreditation organizations are designated will be considered to be grandfathered if the accreditation was granted by an organization that we designate through the process described in proposed § 424.58. These suppliers will not need to be re-accredited until their next regularly scheduled accreditation.

2. Eligibility (Proposed § 414.414(b))

We propose that all bidders must meet eligibility rules to be considered for selection under the Medicare DMEPOS Competitive Bidding Program. The eligibility rules are included in the supplier standards regulation at § 424.57. Also, each bidder must be enrolled with Medicare and be a current supplier, in good standing with the Medicare program, and not under any current Medicare sanctions. Each bidding supplier must certify in its bid that it, its high level employees, chief corporate officers, members of board of directors, affiliated companies and subcontractors are not now and have not been sanctioned by any governmental agency or accreditation or licensing organization. In the alternative, the bidding supplier must disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate

officers, high-level employees, affiliated companies, and subcontractors.

Sanctions would include, but are not limited to, debarment from any Federal program, sanctions issued by the Office of Inspector General, or sanctions issued at the State or local level. In addition, the bidder must have all State and local licenses required to furnish the items that are being bid. Finally, the supplier must agree to all of the terms in the contract outlined in the RFBs. We would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency.

3. Financial Standards (Proposed § 414.414(d))

Section 1847(b)(2)(A)(ii) specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary. Evaluation of financial standards for suppliers assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, we believe that financial standards for suppliers will help maintain beneficiary access to quality services.

Therefore, as part of the bid selection process, the RFBs will identify the specific information we will require to evaluate suppliers, which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency. We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards.

We found that in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency, were important considerations for evaluating financial stability.

As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process.

4. Evaluation of Bids (Proposed § 414.414(e))

We are proposing to select the product categories that include

individual items for which we will require competitive bidding. Individual products will be identified by the Healthcare Common Procedure Coding System (HCPCS Codes) and will be further described in the RFB. Suppliers will be required to submit bids for each individual item within each product category they are seeking to furnish under the program, but will not be required to bid for every product category.

a. Market Demand and Supplier Capacity (Proposed § 414.414(e))

Section 1847(b)(4)(A) of the Act requires that in awarding competitive bidding contracts, the Secretary must select the number of contract suppliers necessary to furnish items to meet the projected demand in the geographic area. Therefore, the first step is for us to determine the expected demand for an item in a competitive bidding area. We propose to calculate expected demand in each competitive bidding area in a relatively straightforward way using existing Medicare claims. We will examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years, and then determine the number of new beneficiaries that have entered the market during the last 2 years. We feel that 2 years worth of data is sufficient to allow us to identify trend analyses and utilization measurements. We will also gather data on the number of new fee-for-service Medicare enrollees coming into a competitive bidding area and use this number to project the number of new enrollees.

We propose to calculate two years worth of claims on a monthly basis to determine beneficiary demand. We will take into consideration the expected demand over the total duration of the contract and the seasonal effects (for example, an increase in beneficiary population in Florida during the winter), and propose to use 2 years of data to identify any time trends. If there are no seasonal effects or time trends, we propose to use the average monthly total and new patient figures as the market demand measures. If there are seasonal effects or changes identified only during certain months, the maximum monthly total and new patient figures would be used as the market demand measures. If trends show that there is noticeable growth or reduction in beneficiary demand for products in an area, we would take these factors into consideration when developing estimates of beneficiary demand for competitively bid items.

We propose to adopt the following approach to estimate supplier capacity

(k) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the item from a contract supplier, payment is made for the item in the amount determined under § 414.416.

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of MSA for CY 2007, CY 2009, and subsequent calendar years.* CMS phases in competitive bidding programs so that competition under the programs occurs in—

(1) Ten of the largest MSAs in CY 2007;

(2) Eighty of the largest MSAs in CY 2009;

(3) Additional areas after CY 2009.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating competitive bidding areas in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service (FFS) beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per FFS beneficiary that received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a competitive bidding area.* CMS may exclude from a competitive bidding area a rural area (as defined in § 412.64(b)(1)(ii)(C) of this chapter), or an area with low population density based on the following factors—

(1) Low utilization of DMEPOS items by Medicare FFS beneficiaries relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare FFS beneficiaries relative to similar geographic areas.

(d) *Selection of additional areas after CY 2009.* (1) Beginning in CY 2010, CMS designates additional competitive bidding areas based on CMS' determination that the implementation of a competitive bidding program in an area is likely to result in significant savings to the Medicare program.

(2) CMS may designate one or more regional or nationwide competitive bidding areas for purposes of implementing competitive bidding programs for items that are furnished through the mail.

§ 414.412 Submission of bids under a competitive bidding program.

(a) In order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must

submit a bid to furnish those items and be awarded a contract under this subpart.

(b) Bids are submitted for items grouped into product categories.

(c) Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program.

(d) Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program.

(e) A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in any area in which a competitive bidding program is implemented which includes the items.

(2) Suppliers that submit one or more bids under paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) *Applicability of the mail order program.* Suppliers that do not furnish items through the mail are not required to participate in a national or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A competitive bidding area, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a competitive bidding area.

§ 414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each bidding supplier must meet the enrollment standards specified in § 424.57 of this chapter.

(2) Each bidding supplier must—

(i) Certify in its bid that it, its high level employees, chief corporate officers, members of its board of directors, its affiliated companies, and its subcontractors are not now and was not sanctioned by any governmental agency or accreditation or licensing organization, or

(ii) Disclose information about any prior or current legal actions, sanctions,

or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

(3) Each bidding supplier must submit with its bid evidence of all State and local licenses required to perform the services identified in its response to the request for bids.

(4) Each bidding supplier must agree to all the terms contained in the request for bids and the supplier contract.

(c) *Quality standards and accreditation.* (1) *Quality standards.* All bidding suppliers must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act.

(2) *Accreditation.* (i) All bidding suppliers must be accredited by a CMS approved accreditation organization, as defined under § 424.57(a) of this chapter.

(ii) A supplier satisfies paragraph (c)(2)(i) of this section if it was accredited by an organization that CMS designates as a CMS-approved accreditation organization under § 424.58 of this chapter.

(d) *Financial standards.* All suppliers must meet the applicable financial standards specified in the request for bids.

(e) *Evaluation of bids.* CMS evaluates bids submitted for a product category by—

(1) Calculating the expected beneficiary demand in a competitive bidding area for items in a product category;

(2) Establishing a composite bid for each supplier that submitted a bid for the product category;

(3) Arraying the composite bids from the lowest to the highest;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all bidding suppliers whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* CMS does not award a contract under this subpart unless CMS determines that the amounts to be paid to a contract supplier for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subparts C or D of this part.

(g) *Sufficient number of suppliers.* If the requirements in paragraphs (e)(5) and (f) of this section are satisfied by two or more suppliers for a product category under a competitive bidding

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 414

[CMS-1270-F]

RIN 0938-AN14

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes competitive bidding programs for certain Medicare Part B covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act. These competitive bidding programs, which will be phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B.

DATES: *Effective Date:* This final rule is effective on June 11, 2007.

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SUPPLEMENTARY INFORMATION:

Electronic Access

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Alphabetical Listing of Acronyms Appearing in This Final Rule

ABN Advance Beneficiary Notice

BBA Balanced Budget Act of 1997, Pub. L. 105-33
 BESS [Medicare] Part B Extract and Summary System
 CBA Competitive bidding area
 CBIC Competitive bidding implementation contractor
 CBSA Core-based statistical area
 CMS Centers for Medicare & Medicaid Services
 CPI-U Consumer Price Index—All Urban Consumers
 CPT [Physician] Current Procedural Terminology, Fourth Edition, 2007, copyrighted by the American Medical Association. CPT® is a trademark of the American Medical Association
 CY Calendar year
 DME Durable medical equipment
 DME MAC Durable Medical Equipment Medicare Administrative Contractor
 DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
 DMERC Durable medical equipment regional carrier
 DRA Deficit Reduction Act of 2005, Pub. L. 109-171
 FAR Federal Acquisition Regulation
 FEHB Federal Employees Health Benefits Program
 FFS Fee-for-service
 FTE Full-time equivalent
 GAO Government Accountability Office
 HCPCS Healthcare Common Procedure Coding System
 HHA Home health agency
 HHS Department of Health and Human Services
 HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191
 IIC Inflation indexed charge
 IRF Inpatient rehabilitation facility
 MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173
 MSA Metropolitan Statistical Area
 NAICS North American Industry Classification System
 NF Nursing facility
 NPWT Negative pressure wound therapy
 NSC National Supplier Clearinghouse
 OBRA '87 Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203
 OIG Office of the Inspector General, HHS
 OTS Off-the-shelf
 PAOC Program Advisory and Oversight Committee
 PEN Parenteral and enteral nutrition
 POV Power-operated vehicle
 RFB Request for bids
 SADMERC Statistical Analysis Durable Medical Equipment Regional Carrier
 SBA Small Business Administration
 SGD Speech generating device
 SNF Skilled nursing facility
 TENS Transcutaneous electrical nerve stimulator

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the supplier being in “good standing” with CMS), including enrollment requirements set forth at §§ 424.500 et seq., during the contract term.

We have added a cross-reference to final § 414.414(b) to indicate that networks (discussed more fully in section XII. of this final rule) must also meet the network requirements found in final § 414.418.

After consideration of public comments, we are finalizing § 414.414(a) without modification. We are finalizing §§ 414.414(b)(1)–(3) with the changes discussed above and with additional technical changes.

C. Financial Standards (§ 414.414(d))

Section 1847(b)(2)(A)(ii) of the Act specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers. Applying financial standards to suppliers assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, we believe that financial standards for suppliers will help maintain beneficiary access to quality services.

Therefore, as part of the bid selection process, we proposed that the RFBs would identify the specific information we will require to evaluate suppliers (proposed § 414.414(d)). We noted that this information may include: a supplier’s bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to fulfill the contract successfully, net worth, and solvency. We welcomed comments on the financial standards, in particular the most appropriate documents that would support these standards. We found that, in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency were important considerations for evaluating financial stability.

Comment: Several comments argued that the financial standards were too strict for certain suppliers and should be flexible enough to regulate mail order suppliers, small local suppliers, SNFs, departments of hospitals, retail pharmacies, and publicly-traded and privately-held family firms. The commenters stated that if financial standards are too restrictive, qualified

suppliers might not be able to participate in the Medicare DMEPOS Competitive Bidding Program. They added that, conversely, if financial standards are too lax, suppliers may be financially unable to meet the challenges of a competitive market.

Response: We have revised proposed § 414.414(d) to indicate that the RFB form will specify the documents required as part of the bid application and that each supplier must submit this documentation along with its bid. We agree with the commenters that it is important to have financial standards that ensure suppliers are able to meet the challenges of competitive bidding and can fulfill their contract obligations. However, we also agree that our financial standards should not be so burdensome that suppliers, and especially small suppliers, cannot satisfy them. After further consideration and in response to comments, we believe that the proposed financial documentation discussed in the preamble to the proposed rule (71 FR 25675) would be too burdensome, particularly for small suppliers. Therefore, in order to obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded) certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian; Equifax; or TransUnion. All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting. This financial information will allow us to determine financial ratios, such as a supplier’s debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier’s financial viability.

We will generally require that suppliers submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter suggested that CMS also publish the criteria it will use to assess supplier’s financial stability and how it will rank suppliers based on these criteria. The commenter stated that bank statements should only be requested when we need to resolve doubts about the supplier’s other submissions. The commenter believed that if we maintain the requirement for bank statements, the statements need to be defined for the period for which we are requesting the financial information.

Response: As we explained above, we recognize that our collection of financial information must be comprehensive enough to allow us to assess a supplier’s financial soundness, but not so burdensome as to encumber the bidding process (especially for small suppliers) and the bid evaluation process. Therefore, as stated above, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of their 10K filing report from the 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded), certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian; Equifax; or TransUnion.

We will generally require that suppliers submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters stated that CMS should consider the supplier’s debt-to-equity ratio (long-term debt divided by shareholders’ equity). They indicated that this is a measurement of a supplier’s capacity to borrow and expand. One commenter indicated, however, that this measurement will be problematic when applied to private firms. The commenters suggested that an alternative would be to require the EBITDA (earnings before interest, taxes, depreciation and amortization)-to-debt ratio because this is more difficult to manipulate. The commenter suggested that CMS could also use the quick ratio (current assets minus inventory divided by current liabilities) because this measurement is favored by lending institutions. Some commenters

indicated that CMS should also define the accounts receivable as the quick ratio (less than 180 days sales outstanding). They indicated that this ratio shows how long it takes the supplier to collect money owed and measures a supplier's liquidity and ability to meet short-term operating needs. Some commenters also suggested that CMS inquire as to how long a supplier has been in business.

Commenters also suggested that the information that CMS collects should include 2 years of financial statements prepared in accordance with generally accepted accounting principles. Some commenters recommended the financial statements be accompanied by a compilation, review, or audit report from an independent certified public accountant, a certificate of insurance verifying a minimum of \$1 million of liability coverage, and a letter from a primary institutional lender verifying current lending relationship and the potential borrowing capacity of the supplier. Commenters also recommended that CMS receive a credit report from a recognized credit rating organization. One commenter wanted CMS to define a set ratio, for example, asset ratio should be not be higher than (X percent) and the asset to liability ratio should be no lower than (X percent).

Response: We will use appropriate financial ratios to evaluate suppliers. If suppliers do not meet certain ratios, they could be disqualified from the competition. Examples of ratios we might consider include a supplier's debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company. The supplier standards in § 424.57(c)(10) require that the supplier carry a \$300,000 comprehensive liability policy. We believe that imposing an additional cost for maintaining \$1 million in liability coverage is not necessary. We will be reviewing all financial information in the aggregate and will not be basing our decision on one ratio but rather overall financial soundness.

As we noted above, we will require for CY 2007 competition that suppliers submit a credit report from one of three credit bureaus identified above to assist in determining a supplier's financial soundness. For all competition rounds, we will specify in the RFB what financial information must be submitted.

Comment: Several commenters recommended that CMS consider using Dunn and Bradstreet accounts payable ratings (paydex score) which measures how quickly a company pays its

accounts payable. The commenters indicated that this information provides an additional measure of whether the supplier is, in fact, able to meet its current obligations.

Response: We will require suppliers to provide us with information which is included on a supplier's credit report when they submit their bids to assist us in determining their financial soundness.

Comment: One commenter argued that CMS must recognize that publicly traded companies are different from privately held community pharmacies, as they have fiduciary obligations to shareholders. Other commenters argued that the financial standards proposed are too burdensome and discourage small suppliers from participating. They recommended that CMS define different standards for small suppliers and pharmacies. The commenters suggested that the standards be limited to credit report, lien searches, credit references and 3 years' worth of tax returns.

Response: We are committed to ensuring the financial soundness of contract suppliers in the competitive bidding program. In previous responses, we have described the financial documentation that will generally be required for the competitions. We have determined that we can obtain the necessary information through collection of a limited number of financial documents and believe that the submission of this information will be less burdensome for all suppliers, including small suppliers. We believe we have balanced the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier.

After consideration of the public comments received, we are revising discussed proposed § 414.414(d) so that it now specifies that a supplier must submit the financial information specified in the RFB. For purposes of the CY 2007 competition, the financial documents discussed in this section will be those that the RFB will require. These requirements are as follows:

- Suppliers that file individual tax returns that include business taxes are required to submit the Schedule C (the Profit and Loss Statement) from their 1040 Tax Return for the 3 years immediately prior to the date on which the bid is submitted. In addition to the tax return information, these suppliers are also required to submit a Compiled Balance Sheet (Statement of Financial Position), a Statement of Cash Flow (Statement of changes in Financial Position) and a Statement of Operations

(Income Statement) for the three years immediately prior to the date on which the bid is submitted. Suppliers are also required to submit a copy of their current credit report, which must have been completed within 90 days prior to the date on which the bid is submitted. The credit report must be prepared by one of the following: Experian; Equifax; or TransUnion.

- Limited partnerships and partnerships must submit their Schedule L from their 1065, U.S. Return of Partnership Income for the 3 years immediately prior to the date on which the bid is submitted, along with all other financial documentation that must be submitted by a supplier that files an individual tax return.

- Suppliers that file corporate tax returns are required to submit the Schedule L (Balance Sheet) from their tax return for the 3 years immediately prior to the date on which the bid is submitted. In addition to the tax return information, these suppliers are also required to submit a Statement of Cash Flow (Statement of Changes in Financial Position), and a Statement of Operations (Income Statement) for the 3 years immediately prior to the date on which the bid is submitted. Suppliers are also required to submit a copy of their current credit report, which must have been completed within 90 days prior to the date on which the supplier submits its bid. The credit report must be prepared by one of the following: Experian; Equifax; or TransUnion.

- All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting.

- Suppliers that are publicly traded companies must additionally submit a copy of their 10-K Filing Reports filed with the Securities Exchange Commission for the 3 years immediately prior to the date on which the bid is submitted. If a supplier is a wholly owned subsidiary of a publicly traded company, it must submit the parent company's 10-K reports.

- If a supplier does not have financial documentation for one or more of the 3 years immediately prior to the date on which the bid is submitted, then in addition to submitting the financial documentation for the years in which it is available, the supplier must also submit projected financial statements. The projected financial statements must show what is likely to occur in the future based on key financial and business assumptions of the present, and must include a description of the financial and business assumptions.

- For networks, the legal entity that submits the bid must submit financial statements on behalf of each network member in one complete package.
- If a supplier is submitting an individual bid and is also part of a network, the supplier must submit financial statements along with both the individual bid and the network bid.

D. Evaluation of Bids (§ 414.414(e))

In the May 1, 2006 proposed rule (71 FR 25675), we proposed to select the product categories that include individual items for which we will require competitive bidding. We stated that individual products would be identified by the HCPCS codes and would be further described in the RFBs. We proposed that suppliers would be required to submit bids for each individual item within each product category they are seeking to furnish under the program, but would not be required to bid for every product category.

1. Market Demand and Supplier Capacity (§§ 414.414(e)(1) and (e)(2))

Section 1847(b)(4)(A) of the Act requires that in awarding competitive bidding contracts, the Secretary may limit the number of contract suppliers in a CBA to the number necessary to furnish items to meet the projected demand for items covered under the contract for the CBA. Therefore, we proposed in proposed § 414.414(e)(1) to calculate expected beneficiary demand in a CBA for items in a product category. We stated that in order to fulfill this statutory mandate, the first step would be to determine the expected demand for an item in a CBA. We proposed to calculate expected demand in each CBA in a relatively straightforward way using existing Medicare claims. We proposed to examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years, and then to determine the number of new beneficiaries who have entered the market during the last 2 years. We believed that 2 years' worth of data would be sufficient to allow us to identify trend analyses and utilization measurements. We also indicated that we would gather data on the number of new FFS Medicare enrollees coming into a CBA and use this number to project the number of new enrollees.

We discussed in the preamble to the May 1, 2006 proposed rule (71 FR 25675) how we proposed to calculate 2 years of claims on a monthly basis to determine beneficiary demand. We stated that we would take into

consideration the expected demand over the total duration of the contract and the seasonal effects (for example, an increase in beneficiary population in Florida during the winter), and proposed to use 2 years of data to identify any time trends. If there were no seasonal effects or time trends, we proposed to use the average monthly total and new patient figures as the market demand measures. However, if there were seasonal effects or changes identified only during certain months, we proposed that the maximum monthly total and new patient figures would be used as the market demand measures. If trends showed that there was noticeable growth or reduction in beneficiary demand for products in an area, we proposed to take these factors into consideration when developing estimates of beneficiary demand for competitively bid items.

We proposed to adopt the following approach to estimate supplier capacity to meet the projected demand in a CBA. First, we proposed to analyze Medicare claims to determine how many items a supplier was currently providing in the CBA, as well as in total. Second, as part of the bid, we would ask suppliers to indicate how many units they were willing and capable of supplying at the bid price in the CBA. We would compare this information to what the supplier has dispensed to Medicare beneficiaries in the past and what it specified in its response to the RFB as its projected capacity. We proposed to require evidence of financial resources to support market expansion, such as letters from investors or lending agents. We would use this information to evaluate the capacity of the bidder. Third, we proposed to compare expected capacity and Medicare volume to determine how many suppliers we would need in an area. For new suppliers, we would ask them for their expected capacity, look at trend data for new suppliers in that area, and examine the capacity of other suppliers in that area. We would need to use these data to make estimates about capacity because we believe that suppliers might have more capacity potential than they are currently exhibiting.

During the DMEPOS competitive bidding demonstrations, demonstration suppliers were able to expand their output to meet market demand and replace market share previously provided by nondemonstration suppliers; indeed, some demonstration suppliers were disappointed that they did not gain more market share during the demonstration. We presented numerous issues to the PAOC where we requested advice on issues such as

market capacity and demands. During the February 28, 2005 PAOC meeting, we asked the panel to discuss the issue of demand and capacity. Several members of the committee, based upon their expertise and knowledge of the industry, suggested that most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor.

We welcomed comments on our proposed approach for calculating market demand and estimating supplier capacity. We were especially interested in any information that would help us compare current Medicare volume with potential capacity, including potential formulas we could apply to determine capacity.

Comment: Several commenters argued that there was insufficient information given as to how CMS will determine a supplier's capacity. The commenters wanted to know if the projected capacity that suppliers must identify in their responses to the RFB form was a bid commitment or estimation. The commenters also noted that CMS did not describe what criteria it will use to compare bidders (aside from bid price) and how these criteria will be applied. They further suggested that CMS look at a supplier's history and allow a 20-percent growth rate to determine the supplier's capacity.

Response: We proposed that suppliers would have to estimate in their response to the RFB how many items they would be able to furnish in the CBA for the bid price. We also proposed that suppliers would be required to submit documentation evidencing any planned business expansion, such as letters from investors or lending agents. We will look at this documentation, as well as the supplier's other financial documentation to determine the ability of that supplier to furnish its projected capacity. The capacity identified in the supplier's response to the RFB form should represent the supplier's best estimation of the number of items it can provide to Medicare beneficiaries in a given CBA. We might, however, make two types of adjustments to a supplier's projected capacity for purposes of finalizing the pivotal bid. First, if a supplier estimates that it can furnish more than 20 percent of what we determine to be the expected beneficiary demand for the product category in the CBA, we will lower that supplier's capacity estimate to 20 percent. We believe that this capacity adjustment is necessary to ensure that at least 5 suppliers have composite bids at or

submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Bids are submitted for items grouped into product categories.

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.

(c) *Furnishing of items.* A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(d) *Separate bids.* For each product category that a supplier is seeking to furnish under a competitive bidding program, the supplier must submit a separate bid for each item in that product category.

(e) *Commonly-owned or controlled suppliers.* (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a

nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

§ 414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in § 424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) *Quality standards and accreditation.* Each supplier must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved accreditation organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.* Each supplier must submit along with its bid the applicable financial documentation specified in the request for bids.

(e) *Evaluation of bids.* CMS evaluates bids submitted for items within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the items in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category;

(3) Establishing a composite bid for each supplier and network that

submitted a bid for the product category.

(4) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(5) Calculating the pivotal bid for the product category;

(6) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under Subpart C or Subpart D.

(g) *Special rules for small suppliers.*

(1) *Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under § 414.416 of this subpart.

(h) *Sufficient number of suppliers.*

(1) Except as provided in paragraph (h)(3) of this section, CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the

seq., nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not

a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 6, 2009.

Lois Rossi,
 Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section § 180.505 is amended by alphabetically adding the following commodities to the tables in paragraphs (a)(1) and (2) to read as follows:

§ 180.505 Emamectin; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Almond, hulls	0.20
* * * * *	*
Nut, tree, group 14	0.02
Pistachio	0.02
* * * * *	*

* * * * *

(2) * * *

Commodity	Parts per million
* * * * *	*
Hog, fat	0.003
Hog, liver	0.020
Hog, meat	0.002
Hog, meat byproducts (except liver)	0.005
* * * * *	*

* * * * *

[FR Doc. E9-625 Filed 1-15-09; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1561-IFC]

RIN 0938-AP59

Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements certain provisions of section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) related to the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Acquisition Program. Specifically, this rule: Implements certain MIPPA provisions that delay implementation of Round 1 of the program; requires CMS to conduct a second Round 1 competition (the “Round 1 rebid”) in 2009; and mandates certain changes for both the Round 1 rebid and subsequent rounds of the program, including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose to CMS information regarding subcontracting relationships.

DATES: Effective date: These regulations are effective on February 17, 2009.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 17, 2009.

ADDRESSES: In commenting, please refer to file code CMS-1561-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” and enter the filecode to find the document accepting comments.

in any year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million. The \$100 million in 1995 dollars is updated annually for inflation and the current expenditure threshold is approximately \$130 million. This rule will not have an effect on the governments mentioned, and the private sector costs would be less than the \$130 million per year threshold. Hence, the Unfunded Mandates Reform Act of 1995 would not apply.

Lastly, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this rule will not have a significant effect on the rights, roles and responsibilities of States.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

■ 2. Section 414.402 is amended by—

■ A. Revising the introductory text of paragraph (1) of the definition of “item.”

■ B. Adding the definitions of “covered document”, “covered document review date” and “hospital”.

§ 414.402 Definitions.

* * * * *

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a

competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

Hospital has the same meaning as in section 1861(e) of the Act.

Item * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

* * * * *

■ 3. Section 414.404 is amended by revising paragraphs (b)(1) introductory text, (b)(1)(ii), and (b)(1)(iii) to read as follows:

§ 414.404 Scope and applicability.

* * * * *

(b) * * *

(1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

* * * * *

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

* * * * *

■ 4. Section 414.408 is amended by revising paragraph (e)(2)(iv) to read as follows:

§ 414.408 Payment rules.

* * * * *

(e) * * *

(2) * * *

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with § 414.404(b) of this subpart.

* * * * *

■ 5. Section 414.410 is amended by revising paragraph (a) as follows:

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—
Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, the additional 70 MSAs selected by CMS as of June 1, 2008.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

* * * * *

■ 6. Section 414.414 is amended by revising paragraph (c) and (d) as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(c) Quality standards and accreditation. Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.*

(1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

(2) *Process for reviewing covered documents.*

(i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.*

(A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1577-F]

RIN 0938-AQ27

Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates and makes certain revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2012. We are also finalizing the interim final rule with comment period published on April 6, 2011, regarding the transition budget-neutrality adjustment under the ESRD PPS. This final rule also sets forth requirements for the ESRD quality incentive program (QIP) for payment years (PYs) 2013 and 2014. In addition, this final rule revises the ambulance fee schedule regulations to conform to statutory changes. This final rule also revises the definition of durable medical equipment (DME) by adding a 3-year minimum lifetime requirement (MLR) that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME. Finally, this final rule implements certain provisions of section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) related to the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) Competitive Acquisition Program and responds to comments received on an interim final rule published January 16, 2009, that implemented these provisions of MIPPA effective April 18, 2009. (See the Table of Contents for a listing of the specific issues addressed in this final rule.)

DATES: *Effective dates:* These regulations are effective on January 1, 2012. Also, effective January 1, 2012, we are finalizing the interim final rule with comment (“Medicare Programs: Changes to the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment”)

published on April 6, 2011 (76 FR 18930). Additionally, effective January 12, 2012 the interim rule amending 42 CFR Part 414, published on January 16, 2009 (74 FR 2873), is confirmed as final.

FOR FURTHER INFORMATION CONTACT:

Terri Deutsch, (410) 786-4533, for issues related to ESRD.
 Roechel Kujawa, (410) 786-9111, for issues related to ambulance services.
 Heidi Oumarou, (410) 786-7942, for issues related to the ESRD market basket.
 Shannon Kerr, (410) 786-3039, for issues related to the quality incentive program.
 Sandhya Gilkerson, (410) 786-4085, for issues related to DME MLR.
 Hafsa Bora, (410) 786-7899 or Ifat Fatima, (410) 786-6709, for DMEPOS Competitive Acquisition Program issues related to comments received on an interim final rule that implemented provisions of MIPPA effective April 18, 2009.

SUPPLEMENTARY INFORMATION:

Addenda Are Only Available Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: <http://www.cms.gov/ESRDPayment/PAY/list.asp>. Readers who experience any problems accessing any of the Addenda to the proposed and final rules that are posted on the CMS Web site identified above should contact Lisa Hubbard at (410) 786-4533.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

- I. Calendar Year (CY) 2012 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
 - A. Background on the End-Stage Renal Disease Prospective Payment System
 - B. Summary of the Proposed Provisions and Responses to Comments on the CY 2012 ESRD PPS
 - 1. Updates to the Composite Rate and ESRD PPS Base Rate
 - a. Composite Rate

- b. ESRD PPS Base Rate
- 2. ESRD Bundled Market Basket
 - a. Overview and Background
 - b. Final Market Basket Update Increase Factor and Labor-Related Share for ESRD Facilities for CY 2012
 - c. Productivity Adjustment
 - d. Calculation of the ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2012
- 3. Transition Budget-Neutrality Adjustment for CY 2011
- 4. Transition Budget-Neutrality Adjustment for CY 2012
- 5. Low-Volume Facility Provisions
- 6. Update to the Drug Add-On to the Composite Rate Portion of the ESRD Blended Payment Rate
 - a. Estimating Growth in Expenditures for Drugs and Biologicals in CY 2012
 - b. Estimating per Patient Growth
 - c. Applying the Growth Update to the Drug Add-On Adjustment
 - d. Update to the Drug Add-On Adjustment for CY 2012
- 7. Updates to the Wage Index Values and Wage Index Floor for the Composite Rate Portion of the Blended Payment and the ESRD PPS Payment
 - a. Reduction to the ESRD Wage Index Floor
 - b. Policies for Areas with no Hospital Data
 - c. Wage Index Budget-Neutrality Adjustment
 - d. ESRD PPS Wage Index Tables
- 8. Drugs
 - a. Vancomycin
 - b. Drug Overfill
- 9. Revisions to Patient-Level Adjustment for Body Surface Area (BSA)
- 10. Revisions to the Outlier Policy
 - a. Revisions Related to Outlier ESRD Drugs and Biologicals
 - b. Exclusion of Automated Multi-Channel Chemistry (AMCC) Laboratory Tests From the Outlier Calculation
 - c. Impact of Final Changes to the Outlier Policy
- D. Technical Corrections
 - 1. Training Add-On
 - 2. ESRD-Related Laboratory Test
- E. Clarifications to the CY 2011 ESRD PPS
 - 1. ICD-9-CM Diagnosis Codes
 - 2. Emergency Services to ESRD Beneficiaries
- F. Miscellaneous Comments
- II. End-Stage Renal Disease Quality Incentive Program for Payment Years (PYs) 2013 and 2014
 - A. Background for the End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014
 - B. Summary of the Proposed Provisions and Responses to Comments on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2013 and PY 2014
 - 1. PY 2013 ESRD QIP Requirements
 - a. Performance Measures for the PY 2013 ESRD QIP
 - b. Performance Period and Case Minimum for the PY 2013 ESRD QIP
 - c. Performance Standards for the PY 2013 ESRD QIP
 - d. Methodology for Calculating the Total Performance Score and Payment Reduction for the PY 2013 ESRD QIP

Addenda will be available only through the Internet. We will continue to post the Addenda through the Internet.

Readers who experience any problems accessing the Addenda that are posted on the CMS Web site at <http://www.cms.gov/ESRDPayment/PAY/list.asp>, should contact Lisa Hubbard at (410) 786-4533.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Proposed Rule to revise the definition of durable medical equipment (DME) to incorporate a minimum lifetime standard of 3 years and further refine the meaning of the term durable.

For the reasons set forth in the preamble, under the authority at 42 U.S.C. 1395hh section 1871 of the Act, the Centers for Medicare & Medicaid Services confirms as final, the interim final rules published on January 16, 2009 (74 FR 2873), and April 6, 2011 (76 FR 18930), and further amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106-113 (133 stat. 1501A-332).

■ 2. Section 413.232 is amended by revising paragraphs (b)(1), (b)(2), and (f) to read as follows:

§ 413.232 Low-volume adjustment.

- (a) * * *
- (b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost

reports, whichever is most recent) preceding the payment year.

* * * * *

(f) Except as provided below, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare administrative contractor that the facility has met all the criteria established in paragraphs (a), (b), (c), and (d) of this section. For calendar year 2012, the attestation must be provided by January 3, 2012.

* * * * *

■ 3. Section 413.237 is amended by adding a new paragraph (a)(1)(v) to read as follows:

§ 413.237 Outliers.

- (a) * * *
- (1) * * *

(v) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 4. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

■ 5. Section 414.202 is amended by revising the definition of “durable medical equipment” to read as follows:

§ 414.202 Definitions.

* * * * *

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

* * * * *

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

- 6. Section 414.402 is amended by—
 - A. Revising the definitions of “covered document” and “covered document review date” and “hospital”.
 - B. Revising the introductory text of paragraph (1) of the definition of “item”.

§ 414.402 Definitions.

* * * * *

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

- (1) The date that is 30 days before the final date for the closing of the bid window; or
- (2) The date that is 30 days after the opening of the bid window.

* * * * *

Hospital has the same meaning as in section 1861(e) of the Act.

Item * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

* * * * *

■ 7. Section 414.404 is amended by revising paragraphs (b)(1) introductory text, (b)(1)(ii), and (b)(1)(iii) to read as follows:

§ 414.404 Scope and applicability.

* * * * *

(b) * * *

(1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

* * * * *

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner

has reassigned the right to receive Medicare payment.

* * * * *

■ 8. Section 414.408 is amended by revising paragraph (e)(2)(iv) to read as follows:

§ 414.408 Payment rules.

* * * * *

(e) * * *

(2) * * *

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with § 414.404(b) of this subpart.

* * * * *

■ 9. Section 414.410 is amended by revising paragraphs (a)(1) through (3) to read as follows:

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

* * * * *

■ 10. Section 414.414 is amended by revising paragraph (c) and (d) as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(c) Quality standards and accreditation. Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the

requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.* (1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

(2) *Process for reviewing covered documents.* (i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.* (A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

* * * * *

■ 11. Section 414.422 is amended by revising paragraph (f) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(f) *Disclosure of subcontracting arrangements.* (1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must

disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

* * * * *

Subpart H—Fee Schedule for Ambulance Services

■ 12. Section 414.610 is amended by revising paragraphs (c)(1) introductory text, (c)(1)(ii), (c)(5)(ii), and (h) to read as follows:

§ 414.610 Basis of payments.

* * * * *

(c) * * *

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.

* * * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2011, ambulance services originating in—

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2011, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008, through December 31, 2011.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

§ 414.400

home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

[75 FR 49202, Aug. 12, 2010]

**Subpart F—Competitive Bidding
for Certain Durable Medical
Equipment, Prosthetics,
Orthotics, and Supplies
(DMEPOS)**

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Affected party means a contract supplier that has been notified that their DMEPOS CBP contract will be terminated for a breach of contract.

Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

Breach of contract means any deviation from contract requirements, including a failure to comply with a governmental agency or licensing organization requirements, constitutes a breach of contract.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers.

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

Corrective action plan (CAP) means a contract supplier's written document

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with supporting information that describes the actions the contract supplier will take within a specified timeframe to remedy a breach of contract.

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

Grandfathered item means all rented items within a product category for which payment was made prior to the implementation of a competitive bidding program to a grandfathered supplier that chooses to continue to furnish the items in accordance with § 414.408(j) of this subpart and that fall within the following payment categories for competitive bidding:

(1) An inexpensive or routinely purchased item described in § 414.220 of this part.

(2) An item requiring frequent and substantial servicing, as described in § 414.222 of this part.

(3) Oxygen and oxygen equipment described in § 414.226 of this part.

(4) Other DME described in § 414.229 of this part.

Grandfathered supplier means a non-contract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Hearing officer (HO) means an individual, who was not involved with the CBIC recommendation to terminate a DMEPOS Competitive Bidding Program contract, who is designated by CMS to review and make an unbiased and independent recommendation when there is an appeal of CMS's initial determination to terminate a DMEPOS Competitive Bidding Program contract.

Hospital has the same meaning as in section 1861(e) of the Act.

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Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Mail order item means any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

National mail order DMEPOS competitive bidding program means a program whereby contracts are awarded to suppliers for the furnishing of mail order items across the nation.

Nationwide competitive bidding area means a CBA that includes the United States, its Territories, and the District of Columbia.

Nationwide mail order contract supplier means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

Network means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

Noncontract supplier means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

Non-mail order item means any item (for example, diabetic testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.

Parties to the hearing means the DMEPOS contract supplier and CMS.

Physician has the same meaning as in section 1861(r) of the Act.

Pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Product category means a grouping of related items that are used to treat a similar medical condition.

Regional competitive bidding area means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

Regional mail order contract supplier means a mail order contract supplier that furnishes items in a regional competitive bidding area.

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Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Small supplier means, a supplier that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73622, Nov. 29, 2010]

§ 414.404 Scope and applicability.

(a) *Applicability*. Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions*. (1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

(i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME, and off-the-shelf (OTS) orthotics.

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

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(2) A physical therapist in private practice (as defined in § 410.60(c) of this chapter) or an occupational therapist in private practice (as defined in § 410.59(c) of this chapter) may furnish competitively bid off-the-shelf orthotics without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with § 414.408(a).

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010]

§ 414.406 Implementation of programs.

(a) *Implementation contractor*. CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) *Competitive bidding areas*. CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas*. CMS may revise the CBAs designated under paragraph (b) of this section.

(d) *Competitively bid items*. CMS designates the items that are included in a competitive bidding program through program instructions or by other means

(e) *Claims processing*. The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

[71 FR 48409, Aug. 18, 2006, as amended at 72 FR 18085, Apr. 10, 2007]

§ 414.408 Payment rules.

(a) *Payment basis*. (1) The payment basis for an item furnished under a competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for

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the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under subpart C or subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another

CBA and the item is included in the competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with §414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items. For contracts entered into beginning on or after January 1, 2011, payment on a lump sum purchase basis is only available for power wheelchairs classified as complex rehabilitative power wheelchairs.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

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(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(h) *Rented equipment*—(1) *Capped rental DME*. Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) For contracts entered into beginning on or after January 1, 2011, the monthly fee schedule amount for rental of power wheelchairs equals 15 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 6 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(3) *Additional payment to certain contract suppliers for capped rental DME*. (i) Except as specified in paragraph (h)(3)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(3)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(4) *Maintenance and servicing of rented DME*. Separate maintenance and serv-

icing payments are not made for any rented durable medical equipment.

(5) *Payment for rented enteral nutrition equipment*. Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. The contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the equipment until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary.

(6) *Maintenance and servicing of rented enteral nutrition equipment*. Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(7) *Payment for inexpensive or routinely purchased durable medical equipment*. Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(8) *Payment amounts for rented DME requiring frequent and substantial servicing*—(i) *General rule*. Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception*. The single payment amounts for continuous passive motion exercise devices are calculated based on the bids submitted and accepted for the furnishing of these items on a daily basis.

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(i) *Monthly payment amounts for oxygen and oxygen equipment*—(1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment*—(1) *Supplier election.* (i) A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the beneficiary maintains a permanent resi-

dence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in § 414.220(a), payment is made in the amount determined under § 414.220(b).

(ii) For other durable medical equipment or capped rental items described in § 414.229, payment is made in the amount determined under § 414.229(b).

(iii) For items requiring frequent and substantial servicing described in § 414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in § 414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in § 414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

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(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Notification of beneficiaries and CMS by suppliers that choose to become grandfathered suppliers.* (i) *Notification of beneficiaries by suppliers.* (A) *Requirements of notification.* A noncontract supplier that elects to become a grandfathered supplier must provide a 30-day written notification to each Medicare beneficiary that resides in a competitive bidding area and is currently renting a competitively bid item from that supplier. The 30-day notification to the beneficiary must meet the following requirements:

(1) Be sent by the supplier to the beneficiary at least 30 business days before the start date of the implementation of the competitive bidding program for the CBA in which the beneficiary resides.

(2) Identify the grandfathered items that the supplier is willing to continue to rent to the beneficiary.

(3) Be in writing (for example, by letter or postcard) and the supplier must maintain proof of delivery.

(4) State that the supplier is willing to continue to furnish certain rented Durable Medical Equipment (DME), oxygen and oxygen equipment, and supplies that the supplier is currently furnishing to the beneficiary (that is, before the start of the competitive bidding program) and is willing to continue to provide these items to the beneficiary for the remaining rental months.

(5) State that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or may elect to receive the item(s) from a contract supplier after the end of the last month for which a rental payment is made to the noncontract supplier.

(6) Provide the supplier's telephone number and instruct the beneficiary to call the supplier with any questions and to notify the supplier of his or her decision to use or not use the supplier as a grandfathered supplier.

(7) State that the beneficiary can obtain information about the competitive bidding program by calling 1-800-

MEDICARE or on the Internet at <http://www.Medicare.gov>.

(B) *Record of beneficiary's choice.* The supplier should obtain an election from the beneficiary regarding whether to use or not use the supplier as a grandfathered supplier. The supplier must maintain a record of its attempts to communicate with the beneficiary to obtain the beneficiary's election regarding grandfathering. When the supplier obtains such an election, the supplier must maintain a record of the beneficiary decision including the date the choice was made, and how the beneficiary communicated his or her choice to the supplier.

(C) *Notification.* If the beneficiary chooses not to continue to receive a grandfathered item(s) from their current supplier, the supplier must provide the beneficiary with 2 more notices in addition to the 30-day notice prior to the supplier picking up its equipment.

(1) *10-day notification:* Ten business days prior to picking up the item, the supplier should have direct contact (for example, a phone call) with the beneficiary or the beneficiary's caregiver and receive acknowledgement that the beneficiary understands their equipment will be picked up. This should occur on the first anniversary date after the start of the CBP or on another date agreed to by the beneficiary or the beneficiary's caregiver. The beneficiary's anniversary date occurs every month and is the date of the month on which the item was first delivered to the beneficiary by the current supplier. When a date other than the anniversary date is chosen by the beneficiary or the beneficiary's caregiver, the noncontract supplier will still receive payment up to the anniversary date after the start of the CBP, and the new contract supplier may not bill for any period of time before the anniversary date.

(2) *2-day notification:* Two business days prior to picking up the item the supplier should contact the beneficiary or the beneficiary's caregiver by phone to notify the beneficiary of the date the supplier will pick up the item. This date should not be before the beneficiary's first anniversary date that occurs after the start of the competitive

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bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(D) *Pickup procedures.* (1) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(2) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(3) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are suitable to the beneficiary.

(4) The contract supplier may not submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP, and the contract supplier may not begin billing until the first anniversary date that occurs after the beginning of the CBP.

(5) The noncontract supplier must submit a claim to be paid up to the first anniversary date that occurs after the beginning of the CBP. Therefore, they should not pick up the equipment before that date unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(ii) *Notification to CMS by suppliers.* A noncontract supplier that elects to become a grandfathered supplier must provide a written notification to CMS of this decision. This notification must meet the following requirements:

(A) State that the supplier agrees to continue to furnish certain rented DME, oxygen and oxygen equipment that it is currently furnishing to beneficiaries (that is, before the start of the competitive bidding program) in a CBA

and will continue to provide these items to these beneficiaries for the remaining months of the rental period.

(B) Include the following information:

(1) Name and address of the supplier.

(2) The 6-digit NSC number of the supplier.

(3) Product category(s) by CBA for which the supplier is willing to be a grandfathered supplier.

(C) State that the supplier agrees to meet all the terms and conditions pertaining to grandfathered suppliers.

(D) Be provided by the supplier to CMS in writing at least 30 business days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.

(6) *Suppliers that choose not to become grandfathered suppliers.* (i) *Requirement for non-grandfathered supplier.* A noncontract supplier that elects not to become a grandfathered supplier is required to pick up the item it is currently renting to the beneficiary from the beneficiary's home after proper notification.

(ii) *Notification.* Proper notification includes a 30-day, a 10-day, and a 2-day notice of the supplier's decision not to become a grandfathered supplier to its Medicare beneficiaries who are currently renting certain DME competitively bid item(s) and who reside in a CBA.

(iii) *Requirements of notification.* These notifications must meet all of the requirements listed in paragraph (j)(5)(i) of this section for the 30-day, 10-day and 2-day notices that must be sent by suppliers who decide to be grandfathered suppliers, with the following exceptions for the 30-day notice.

(A) State that, for those items for which the supplier has decided not to be a grandfathered supplier, the supplier will only continue to rent these competitively bid item(s) to its beneficiaries up to the first anniversary date that occurs after the start of the Medicare DMEPOS Competitive Bidding Program.

(B) State that the beneficiary must select a contract supplier for Medicare to continue to pay for these items.

(C) Refer the beneficiary to the contract supplier locator tool on and to 1-800-MEDICARE to obtain information

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about the availability of contract suppliers for the beneficiary's area.

(iv) *Pickup procedures.* (A) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(B) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(C) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are agreeable to the beneficiary.

(D) The contract supplier cannot submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP.

(7) *Payment for accessories and supplies for grandfathered items.* Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items.* (1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with §414.210(e)(1) of subpart D.

(ii) Payment for parts that are not items (as defined in §414.402) is made in accordance with §414.210(e)(1) of subpart D.

(iii) Payment for parts that are items (as defined in §414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with §414.210(e)(2), (e)(3) and (e)(5) of this part for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for the replacement item in accordance with paragraph (a)(1) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73623, Nov. 29, 2010]

§414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

(4) For competitions (other than for national mail order items and services) after CY 2011 and prior to CY 2015, the following areas are excluded:

(i) Rural areas.

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(ii) MSAs not selected under paragraphs (a)(1) or (a)(2) of this section with a population of less than 250,000.

(iii) An area with low population density within an MSA not selected under paragraphs (a)(1) or (a)(2) of this section.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in § 412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010]

§ 414.411 Special rule in case of competitions for diabetic testing strips conducted on or after January 1, 2011.

(a) *National mail order competitions.* A supplier must demonstrate that their bid submitted as part of a national mail order competition for diabetic testing strips covers the furnishing of a sufficient number of different types of diabetic testing strip products that, in the aggregate, and taking into account volume for the different products, includes at least 50 percent of all the different types of products on the market. A type of diabetic testing strip means a specific brand and model of testing strips.

(b) *Other competitions.* CMS may apply this special rule to non-mail order or local competitions for diabetic testing strips.

[75 FR 73623, Nov. 29, 2010]

§ 414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under § 414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Bids are submitted for items grouped into product categories.

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.

(c) *Furnishing of items.* A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(d) *Separate bids.* For each product category that a supplier is seeking to furnish under a competitive bidding program, the supplier must submit a separate bid for each item in that product category.

(e) *Commonly-owned or controlled suppliers.* (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

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(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

[72 FR 18085, Apr. 10, 2007]

§414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in §424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in §414.418.

(c) *Quality standards and accreditation.* Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of §424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards—(1) General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in §414.402) specified in the request for bids.

(2) *Process for reviewing covered documents—(i) Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents—(A) For*

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Round 1 bids. CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to provide notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

(e) *Evaluation of bids.* CMS evaluates bids submitted for items within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the items in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category;

(3) Establishing a composite bid for each supplier and network that submitted a bid for the product category.

(4) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(5) Calculating the pivotal bid for the product category;

(6) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or Subpart D.

(g) *Special rules for small suppliers—(1) Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a

competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under § 414.416 of this subpart.

(h) *Sufficient number of suppliers.* (1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under § 414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

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(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009]

§414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for an item furnished under a competitive bidding program is equal to the median of the bids submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. If there is an even number of bids, the single payment amount for the item is equal to the average of the two middle bids.

(2) The single payment amount for an item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C or subpart D.

[72 FR 18085, Apr. 10, 2007]

§414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

(b) The following rules apply to networks that seek contracts under this subpart:

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(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in §414.414(b) through (d).

(3) A small supplier may join one or more networks but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member of more than one network if those networks submit bids to furnish the same product category in the same CBA.

(4) The network cannot be anti-competitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

[72 FR 18085, Apr. 10, 2007]

§414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under

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a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item or mode of delivery prescribed.* A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that submits a claim prohibited by this paragraph.

[72 FR 18085, Apr. 10, 2007]

§ 414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items that the contract supplier makes available to other customers.

(d) *Change of ownership.* (1) A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change.

(2) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if—

(i) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) The successor entity submits to CMS the documentation described under § 414.414(b) through (d) if that documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. This documentation must be submitted within 30 days prior to the anticipated effective date of the change of ownership. A successor entity is not required to duplicate previously submitted information if the previously submitted information is still current;

(iii) The successor entity is acquiring the assets of the existing contract supplier, it submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(iv) A new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph

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(d)(2)(iii) of this section for CMS review. The successor entity must submit to CMS, within 30 days after the effective date of the change of ownership and executed novation agreement acceptable to CMS.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(3) Contract suppliers for diabetic testing supplies must furnish the brand of diabetic testing supplies that work with the home blood glucose monitor selected by the beneficiary. The contract supplier is prohibited from influencing or incentivizing the beneficiary by persuading, pressuring, or advising them to switch from their current brand or for new beneficiaries from their preferred brand of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

(f) *Disclosure of subcontracting arrangements*—(1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award

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with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

(g) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions:

(i) Require the contract supplier to submit a corrective action plan;

(ii) Suspend the contract supplier's contract;

(iii) Terminate the contract;

(iv) Preclude the contract supplier from participating in the competitive bidding program;

(v) Revoke the supplier number of the contract supplier; or

(vi) Avail itself of other remedies allowed by law.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2881, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010]

§ 414.423 Appeals Process for Termination of Competitive Bidding Contract.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contracts and where CMS has taken action to terminate the supplier's contract. Except as specified in this regulation termination decisions made under this section are final and binding.

(a) *Terminations for breach of contract.* CMS may terminate a supplier's DMEPOS Competitive Bidding Program contract when it determines that the supplier has violated any of the terms of its contract.

(b) *Notice of termination.* (1) *CMS notification.* If CMS determines a supplier to be in breach of its contract either in part or in whole, it will notify the Medicare DMEPOS supplier of the termination by certified mail.

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(2) *Content of the notice.* The CMS notice will include the following:

- (i) The reasons for the termination.
- (ii) The right to request a hearing by a CBIC Hearing Officer, and depending on the nature of the breach, the supplier may also be allowed to submit a CAP in lieu of requesting a hearing by a CBIC Hearing Officer, as specified in paragraph (c)(1)(i) of this section.
- (iii) The address to which the written request for a hearing must be mailed.
- (iv) The address to which the CAP must be mailed, if applicable.
- (v) Penalties that will accompany the termination, such as not being eligible to bid in future rounds of competitive bidding.
- (vi) The effective date of termination is 45 days from the date of the notification letter unless a timely hearing request has been filed or a corrective action plan (CAP) has been submitted within 30 days of the date on the notification letter.

(c) *Corrective action plan (CAP)—(1) Option for corrective action plan (CAP).*

(i) CMS has the option to allow a DMEPOS supplier to provide a written corrective action plan (CAP) to remedy the deficiencies identified in the notice, when CMS determines that the delay in the termination date caused by allowing a CAP will not cause harm to beneficiaries, for example, we would not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime.

(ii) If a supplier chooses not to submit a CAP or if CMS determines that a supplier's CAP is insufficient, the supplier may request a hearing on the termination.

(2) *Submission of a CAP.* (i) A corrective action plan must be submitted within 30 days from the date on the notification letter. If the supplier decides not to submit a corrective action plan the supplier may within 30 days of the date on the termination letter request a hearing by a CBIC hearing officer.

(ii) Suppliers will only have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable or prop-

erly implemented, suppliers will receive a subsequent termination notice.

(d) *The purpose of the corrective action plan.* (1) For the supplier to eliminate all of the deficiencies that were identified in the notice to terminate its contract to avoid contract termination.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one-time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as identified in the notice of termination.

(2) If CMS accepts the CAP, including supplier's designated timeframe for its completion; the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement an acceptable CAP the supplier will receive a subsequent notice that their contract will be terminated within 45 days of the date on that notice.

(f) *Right to request a hearing by the CBIC hearing officer (HO).* (1) A supplier who has received a notice that CMS considers the supplier in breach of contract or that the supplier's CAP is not acceptable has the right to request a hearing before an HO who was not involved with the original determination.

(2) A supplier who wishes to appeal the termination notice must submit a written request to the CBIC. The request for a hearing must be received by the CBIC within 30 days from the date of the notice to terminate.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of the Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is

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not submitted and the supplier fails to timely request a hearing, this will result in the termination of the supplier's DMEPOS Competitive Bidding Program contract effective 45 days from the date on the notice to terminate received by the supplier.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the supplier's request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the supplier 30 days before the date of the hearing.

(4) The HO may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days notice of the change.

(5) The HO's scheduling notice must provide the parties to the hearing and the CBIC the following information:

(i) Description of the hearing procedure.

(ii) The general and specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the HO.

(v) All evidence submitted, both from the supplier and CMS, in preparation for the hearing with all affected parties within 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the HO with convincing evidence that it has not breached its contract or that termination is not appropriate.

(2) The supplier's supporting evidence must be submitted with its request for a hearing.

(3) If the Medicare DMEPOS supplier fails to submit this evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from in-

roducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the HO within 10 days of receiving a notice announcing the hearing.

(5) The HO will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing and the CBIC within 15 days prior to the scheduled date of the hearing.

(i) *Role of the Hearing Officer.* The HO will conduct a thorough and independent review of the evidence including the information and documentation submitted for the hearing and other information that the HO considers pertinent for the hearing. The role of the HO includes, at a minimum, the following:

(1) Conducts the hearing and decides the order in which the evidence and the arguments of the parties are presented;

(2) Determines the rules on admissibility of the evidence;

(3) Examines the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties.

(5) Determines the rules for requesting documents and other evidence from other parties;

(6) Ensures a complete record of the hearing is made available to all parties to the hearing;

(7) Prepares a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the HO and considered as part of the hearing; and

(8) Complies with all applicable provisions of 42 USC Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing Officer recommendation.* (1) The HO will issue a written recommendation to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the HO has demonstrated that an

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extension is needed due to the complexity of the matter or heavy workload.

(2) The recommendation will explain the basis and the rationale for the HO's recommendation.

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced during the hearing along with its recommendation.

(k) *CMS' final determination.* (1) CMS' review of the HO recommendation will not allow the supplier to submit new information.

(2) After reviewing the HO recommendation, CMS' decision will be made within 30 days from the date of receipt of the HO's recommendation.

(3) A CMS decision to terminate will indicate the effective date of the termination.

(4) This decision is final and binding.

(1) *Effect of contract termination.* A contract supplier whose contract has been terminated—

(1) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

(2) Must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(i) The notice to the beneficiary from the supplier whose contract was terminated must be provided within 15 days of receipt of the final notice of termination.

(ii) The notification to the beneficiaries must inform the beneficiaries that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay these items.

(m) *Effective date of the contract termination.* (1) A supplier's DMEPOS CBP contract is terminated effective on the termination date specified in the notice to the supplier, unless the supplier timely requests a hearing with the HO or the supplier has submitted a CAP under paragraph (c) of this section.

(2) If a supplier requests an HO review of the CMS decision to terminate its contract, and CMS based upon the

HO's recommendation terminates the supplier's contract, the effective date of the termination will be the date specified in the post-hearing notice to the supplier indicating CMS's final determination to terminate the contract.

(3) For violations of the terms of the supplier's DMEPOS CBP contract that may harm beneficiaries, such as a supplier providing an inferior product that causes harm to the beneficiary, no delays of the effective date of the termination will be allowed.

[75 FR 73623, Nov. 29, 2010]

§ 414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

[72 FR 18085, Apr. 10, 2007]

§ 414.425 Claims for damages.

(a) *Eligibility for filing a claim for damages as a result of the termination of supplier contracts by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).* (1) Any aggrieved supplier, including a member of a network that was awarded a contract for the Round 1 Durable Medical Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) that believes it has been damaged by the termination of its competitive bid contract, may file a claim under this section.

(2) A subcontractor of a contract supplier is not eligible to submit a claim under this section.

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(b) *Timeframe for filing a claim.* (1) A completed claim, including all documentation, must be filed within 90 days of January 1, 2010 (the effective date of these damages provisions), unless that day is a Federal holiday or Sunday in which case it will fall to the next business day.

(2) The date of filing is the actual date of receipt by the CBIC of a completed claim that includes all the information required by this rule.

(c) *Information that must be included in a claim.* (1) Supplier's name, name of authorized official, U.S. Post Office mailing address, phone number, email address and bidding number, and National Supplier Clearinghouse Number;

(2) A copy of the signed contract entered into with CMS for the Round 1 DMEPOS Competitive Bidding Program;

(3) A detailed explanation of the damages incurred by this supplier as a direct result of the termination of the Round 1 competitive bid contract by MIPPA. The explanation must include all of the following:

(i) Documentation of the supplier's damages through receipts.

(ii) Records that substantiate the supplier's damages and demonstrate that the damages are directly related to performance of the Round 1 contract and are consistent with information the supplier provided as part of their bid.

(4) The supplier must explain how it would be damaged if not reimbursed.

(5) The claim must document steps the supplier took to mitigate any damages they may have incurred due to the contract termination, including a detailed explanation of the steps of all attempts to use for other purposes, return or dispose of equipment or other assets purchased or rented for the use in the Round 1 DMEPOS CBP contract performance.

(d) *Items that will not be considered in a claim.* The following items will not be considered in a claim:

(1) The cost of submitting a bid.

(2) Any fees or costs incurred for consulting or marketing.

(3) Costs associated with accreditation or licensure.

(4) Costs incurred before March 20, 2008.

(5) Costs incurred for contract performance after July 14, 2008 except for costs incurred to mitigate damages.

(6) Any profits a supplier may have expected from the contract.

(7) Costs that would have occurred without a contract having been awarded.

(8) Costs for items such as inventory, delivery vehicles, office space and equipment, personnel, which the supplier did not purchase specifically to perform the contract.

(9) Costs that the supplier has recouped by any means, and may include use of personnel, material, suppliers, or equipment in the supplier's business operations.

(e) *Filing a claim.* (1) A claim, with all supporting documentation, must be filed with the CMS Competitive Bidding Implementation Contractor (CBIC).

(2) Claims must include a statement from a supplier's authorized official certifying the accuracy of the information provided on the claim and all supporting documentation.

(3) The CBIC does not accept electronic submissions of claims for damages.

(f) *Review of claim.* (1) *Role of the CBIC.* (i) The CBIC will review the claim to ensure it is submitted timely, complete, and by an eligible claimant. When the CBIC identifies that a claim is incomplete or not filed timely, it will make a recommendation to the Determining Authority not to process the claim further. Incomplete or untimely claims may be dismissed by the Determining Authority without further processing.

(ii) For complete, timely claims, the CBIC will review the claim on its merits to determine if damages are warranted and may seek further information from the claimant when making its recommendation to the Determining Authority. The CBIC may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iii) The CBIC will make a recommendation to the Determining Authority for each claim filed and include an explanation that supports its recommendation.

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(iv) The recommendation must be either to award damages for a particular amount (which may not be the same amount requested by the claimant) or that no damages should be awarded.

(A) If the CBIC recommends that damages are warranted, the CBIC will calculate a recommended reasonable amount of damages based on the claim submitted.

(B) The reasonable amount will consider both costs incurred and the contractor's attempts and action to limit the damages;

(v) The recommendation will be sent to the Determining Authority for a final determination.

(2) *CMS' role as the Determining Authority.* (i) The Determining Authority shall review the recommendation of the CBIC.

(ii) The Determining Authority may seek further information from the claimant or the CBIC in making a concurrence or non-concurrence determination.

(iii) The Determining Authority may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iv) If the Determining Authority concurs with the CBIC recommendation, the Determining Authority shall submit a final signed decision to the CBIC and direct the CBIC to notify the claimant of the decision and the reasons for the final decision.

(v) If the Determining Authority non-concurs with the CBIC recommendation, the Determining Authority may return the claim for further processing or the Determining Authority may:

(A) Write a determination granting (in whole or in part) a claim for damages or denying a claim in its entirety;

(B) Direct the CBIC to write said determination for the Determining Authority's signature; or

(C) Return the claim to the CBIC with further instructions.

(vi) The Determining Authority's determination is final and not subject to administrative or judicial review.

(g) *Timeframe for determinations.* (1) Every effort will be made to make a determination within 120 days of initial receipt of the claim for damages by the

CBIC or the receipt of additional information that was requested by the CBIC, whichever is later.

(2) In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

(h) *Notification to claimant of damage determination.* The CBIC must mail the Determining Authority's determination to the claimant by certified mail return receipt requested, at the address provided in the claim.

[74 FR 62011, Nov. 25, 2009]

§ 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for

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these items will be made in accordance with Subpart C or Subpart D.

[72 FR 18085, Apr. 10, 2007]

Subpart G—Payment for New Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act—procedures for determining the basis for, and amount of, payment for a new clinical diagnostic laboratory test with respect to which a new or substantially revised Healthcare Common Procedure Coding System code is assigned on or after January 1, 2005.

§ 414.502 Definitions.

For purposes of this subpart—

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.504 [Reserved]

§ 414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new test, CMS determines the basis for and amount of payment after performance of the following:

(a) CMS makes available to the public (through CMS's Internet Web site) a list that includes codes for which establishment of a payment amount is being considered for the next calendar year.

(b) CMS publishes a FEDERAL REGISTER notice of a meeting to receive public comments and recommendations

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(and data on which recommendations are based) on the appropriate basis, as specified in § 414.508, for establishing payment amounts for the list of codes made available to the public.

(c) Not fewer than 30 days after publication of the notice in the FEDERAL REGISTER, CMS convenes a meeting that includes representatives of CMS officials involved in determining payment amounts, to receive public comments and recommendations (and data on which the recommendations are based).

(d) Considering the comments and recommendations (and accompanying data) received at the public meeting, CMS develops and makes available to the public (through an Internet Web site and other appropriate mechanisms) a list of—

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.508 Payment for a new clinical diagnostic laboratory test.

For a new clinical diagnostic laboratory test that is assigned a new or substantially revised code on or after January 1, 2005, CMS determines the payment amount based on either of the following:

(a) *Crosswalking*. Crosswalking is used if it is determined that a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(1) CMS assigns to the new test code, the local fee schedule amounts and national limitation amount of the existing test.

(2) Payment for the new test code is made at the lesser of the local fee