

### Update on Stark Gainsharing Exception

Despite its enthusiasm to craft an exception to the Stark Law for shared savings programs like gainsharing and pay-for-performance (P4P) arrangements, CMS delayed finalizing such an exception in the 2009 Medicare Physician Fee Schedule (MPFS) Final Rule.<sup>1</sup> In the Final Rule, issued on October 30, 2009, CMS stated that it had received too few comments to craft an appropriate exception for shared savings programs that would not risk fraud to the Medicare program.

One primary opponent of the exception is the medical device industry. The Advanced Medical Technology Association (AdvaMed), a medical technology group, believes that gainsharing arrangements may create incentives for the use of less-expensive or older medical technologies.<sup>2</sup> Because gainsharing is a way to provide incentive payment and cost-savings to be shared with physicians, board chairman of AdvaMed, Michael A. Mussallem, praised the decision to not finalize the exception, expressing concern that gainsharing arrangements may “*compromise patient care by creating incentives for the use of less-expensive, older, outdated technologies when newer, better, technologies might be more appropriate.*”<sup>3</sup> He went on to state that “*patients also may receive less care than appropriate under such a proposal.*” Mussallem, who also happens to be chairman and chief executive officer of Edwards Lifesciences, said also that the medical device industry would prefer that CMS review and completely evaluate the congressionally mandated gainsharing demonstration, along with two other demonstrations, before finalizing the exception to the Stark Law.<sup>4</sup>

According to the MPFS Proposed Rule, published on July 7, 2008, CMS believes that shared savings programs have the potential to “*foster high quality, cost-effective care*”<sup>5</sup> but it also expressed concerns similar to those being voiced by the medical device industry over the issue of *stinting*, or “*limiting the use of quality-improving but more costly devices, tests or treatments.*”<sup>6</sup> While CMS stated that the majority of the comments it did receive in response to the Proposed Rule favored the exception, it noted that many of those responses only favored finalizing the exception if substantial modifications were made to the originally proposed program conditions.<sup>7</sup> Though it received numerous comments, CMS did not receive enough comments in agreement about how the exception should be structured, and accordingly, CMS has issued the rule with another

comment period, soliciting further comments from the health care community so that it may finalize the exception in the future. Ultimately, CMS would like to develop an exception that “*would meet the ‘no risk’ standard, would be sufficiently bright line to be enforceable and to facilitate compliance, and would be sufficiently flexible to foster beneficiary arrangements.*”<sup>8</sup>

The Final Rule is set to be published in the *Federal Register* on November 19, 2008, and CMS will accept comments on this exception for 90 days after that date.<sup>9</sup>

<sup>1</sup> “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule with Comment Period,” Department of Health and Human Services, Center for Medicare and Medicaid Services, October 30, 2008, available at <http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1403-FC.pdf?agree=yes&next=Accept>. (Accessed 11/11/08).

<sup>2</sup> “CMS Seeks More Comments on Proposed Self-Referral Exception for Shared Savings,” BNA Health Law Reporter, 17 HLR 1449, Nov. 6, 2008.

<sup>3</sup> “CMS Seeks More Comments on Proposed Self-Referral Exception for Shared Savings,” BNA Health Law Reporter, 17 HLR 1449, Nov. 6, 2008.

<sup>4</sup> “CMS Seeks More Comments on Proposed Self-Referral Exception for Shared Savings,” BNA Health Law Reporter, 17 HLR 1449, Nov. 6, 2008.

<sup>5</sup> Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule,” 73 Fed. Reg. 38502, 38548, Department of Health and Human Services, Center for Medicare and Medicaid Service, July 7, 2008.

<sup>6</sup> “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule with Comment Period,” Department of Health and Human Services, Center for Medicare and Medicaid Services, October 30, 2008, available at <http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1403-FC.pdf?agree=yes&next=Accept>. (Accessed 11/11/08).

<sup>7</sup> “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule with Comment Period,” Department of Health and Human Services, Center for Medicare and Medicaid Services, October 30, 2008, available at <http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1403-FC.pdf?agree=yes&next=Accept>. (Accessed 11/11/08).

<sup>8</sup> “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule with Comment Period,” Department of Health and Human Services, Center for Medicare and Medicaid Services, October 30, 2008, available at <http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1403-FC.pdf?agree=yes&next=Accept>. (Accessed 11/11/08).

<sup>9</sup> “Final 2009 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule,” Centers for Medicare and Medicaid Services, Oct. 30, 2008, <http://www.cms.hhs.gov/pf/printpage.asp?ref=http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3333&chkNewsType=6&intPage=&intNumPerPage=10&srchOpt=0&checkDate=&checkKey=&pYear=&srchType=1&numDays=3500&showAll=&srchData=&keywordType=All&year=&cboOrder=date&de se=> (Accessed 11/18/08).



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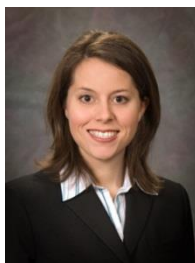
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