HEALTH REFORM READINESS: Opportunities & Challenges for Your Organization

### **HEALTH CARE & LIFE SCIENCES**

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December 2, 2011

#### Medicare Providers and Suppliers Continue in the Spotlight: Expansion of the DMEPOS Competitive Bidding Program; Legislative Inquiry Related to Fraud and Abuse Enforcement Actions; and Automated Pre-Enrollment Provider Screening

#### **RESOURCE LINKS**

Details regarding the timeline can be found on:

<u>CMS website:</u> http://www.cms.hhs.gov

Competitive <u>Bidding Implementation Contractor</u> (<u>"CBIC"</u>) website: http://www.dmecompetitivebid.com

#### **IMPORTANT DATES**

#### **DMEPOS Competitive Bidding:**

<u>November 30, 2011:</u> CMS announced the bidding timeline for the Round 2 and national mail-order competitions

<u>December 5, 2011:</u> Supplier registration for user IDs and passwords begins

<u>December 22, 2011:</u> Authorized Officials strongly encouraged to register no later than this date

In order to be prepared for upcoming changes and to respond to new initiatives, providers and suppliers participating in Medicare must be aware of recent Congressional activity that would hold the federal government accountable for intended its enforcement efforts designed to curb health care fraud, waste, and abuse, as well as an effort by the Centers for Medicare & Medicaid Services ("CMS") to implement automated pre-enrollment provider and supplier screening in January 2012. One example of the pressures that providers and suppliers face in this enhanced regulatory and enforcement climate is the upcoming expansion of Durable Medical Equipment, the Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program, which is targeted to launch in July 2013 and for which the Round 2 bidding timeline was announced on November 30, 2011.

Expansion of DMEPOS Competitive Bidding Program – Round 2 Details and Timeline Announced

In late August, CMS released select details regarding Round 2 of the DMEPOS Competitive Bidding Program ("Program"), including confirmation of the Round 2 product categories.<sup>1</sup> Round 2 of the Program, for which bidding is

<sup>&</sup>lt;sup>1</sup> Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Program Expansion Announced," Aug. 19, 2011, *available at bttps://www.cms.gov/DMEPOSCompetitiveBid/0101\_Announcements\_and\_Communications\_aspt#TopOfPage* 

https://www.cms.gov/DMEPOSCompetitiveBid/01A1\_Announcements\_and\_Communications.asp#TopOfPage.

#### **IMPORTANT DATES**

January 2012: Automate pre-enrollment provider screening

<u>February 9, 2012:</u> Supplier registration ends

January 30, 2012: Bid window opens

March 30, 2012: Bid window closes

<u>Fall 2012:</u> CMS expects to announce single contracting process

Spring 2013: Contract suppliers expected to be announced

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targeted to begin in the winter of 2012, includes substantial expansion into 91 additional metropolitan statistical areas ("MSAs")<sup>2</sup> and is targeted to launch in <u>July 2013</u>.<sup>3</sup> CMS began its pre-bidding supplier awareness program in the summer of 2012.<sup>4</sup> In addition to launching Round 2, CMS reported that it also will begin to conduct a national mail-order competition for diabetic testing supplies at the same time.<sup>5</sup>

#### Items Covered in Round 2

All of the product categories selected for inclusion in Round 2 are deemed by CMS to be high-cost and high-volume items.<sup>6</sup> The eight product categories selected for Round 2 are:

- Oxygen, oxygen equipment, and supplies;
- Standard (power and manual) wheelchairs, scooters, and related accessories;
- Enteral nutrients, equipment, and supplies;
- Continuous positive airway pressure ("CPAP") devices and respiratory assist devices ("RADs") and related supplies and accessories;
- Hospital beds and related accessories;
- Walkers and related accessories;
- Negative pressure wound therapy pumps and related supplies and accessories; and

<sup>&</sup>lt;sup>2</sup> MSAs are areas designated by the Office of Management and Budget ("OMB") that include major cities and the suburban areas surrounding them. By contrast, a competitive bidding area ("CBA") is defined by specific zip codes related to an MSA. A CBA may be concurrent with, larger than, or smaller than the related MSA, depending on a variety of considerations (*e.g.,* the exclusion of low population-density areas within an MSA or the inclusion of areas outside an MSA that are part of a normal service area for suppliers in that MSA). A CBA will be the area wherein only contract suppliers may furnish certain DMEPOS items to beneficiaries unless an exception is permitted by regulations. In January 2008, CMS announced 70 MSAs for Round 2. The Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") requires that Round 2 occur in these MSAs. In 2010, ACA added 21 additional MSAs to the original 70 MSAs for Round 2, for a total of 91 MSAs for Round 2. ACA specifies that the additional 21 MSAs must "include the next 21 largest metropolitan statistical areas by total population" after those already selected for Round 2 of the Program. A complete list of the Round 2 MSAs and information about the associated CBAs are available at https://www.cms.gov/DMEPOSCompetitiveBid/01a MSAs and CBAs.asp#TopOfPage.

<sup>&</sup>lt;sup>3</sup> BNA, "CMS Releases DME Product Categories, Other Info on Round Two of Bidding Program," Aug. 22, 2011. <sup>4</sup> Id

<sup>&</sup>lt;sup>5</sup> Id.

<sup>6</sup> Centers for Medicare & Medicaid Services, "Next Steps for Expansion of the Medicare Durable Medical Equipment, Orthotics, and Supplies Competitive Bidding Program," Aug. 19. available Prosthetics. 2011. at https://www.cms.gov/apps/media/press/factsheet.asp?Counter=4065&intNumPerPage=10&checkDate=&checkKey=&src hType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&ye ar=&desc=&cboOrder=date.

• Support surfaces (Group 2 mattresses and overlays).<sup>7</sup>

#### Round 2 Bidding Timeline Announced

On November 30, 2011, CMS announced the bidding timeline for the Round 2 and national mail-order competitions.<sup>8</sup> Details regarding the timeline can be found on both the CMS website (http://www.cms.hhs.gov) and the Competitive Bidding Implementation Contractor ("CBIC") website (http://www.dmecompetitivebid.com). Additionally, in preparation for the bidding period, CMS has launched a comprehensive bidder education program.<sup>9</sup> Importantly, supplier registration for user IDs and passwords begins next week (December 5, 2011) and ends on February 9, 2012, with Authorized Officials strongly encouraged to register no later than December 22, 2011.<sup>10</sup> The bid window opens on January 30, 2012, and closes on March 30, 2012. CMS expects to announce single payment amounts and begin the contracting process in the fall of 2012, and contract suppliers are expected to be announced in the spring of 2013.<sup>11</sup> As discussed below, the competitive bidding program has not been without criticism. However, Jonathan Blum, Deputy CMS Administrator and Director of the Center for Medicare, stated, "We have considered feedback from many stakeholders to implement process improvements to make the competitive bidding program even stronger. In addition to the enhancements we've made to our bidder education program, we will be strengthening our rigorous bid evaluation process by increasing our scrutiny of bids."<sup>12</sup>

As it has been in the past, CBIC will be the primary source for bidder education.<sup>13</sup> Suppliers should visit the CBIC website for information regarding the bidding process. Specifically, the website includes information relating to bidding rules, webcasts, user guides, policy fact sheets, checklists, and bidding information charts.<sup>14</sup> Many of these materials already have been updated and suppliers should be aware of new and updated information for Round 2 and the national mail-order competition. According to CMS, the bidder education program "will feature numerous enhancements such as the

<sup>&</sup>lt;sup>7</sup> Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Program Expansion Announced," Aug. 19, 2011, *available at* 

https://www.cms.gov/DMEPOSCompetitiveBid/01A1\_Announcements\_and\_Communications.asp#TopOfPage.

<sup>&</sup>lt;sup>8</sup> Centers for Medicare & Medicaid Services, "Medicare Announces Timeline, Starts Bidder Education for Durable Medical Equipment, Prosthetics, Orthotics and Supplies – Competitive Bidding Program Round 2 and National Mail-Order Competitions," Nov. 30, 2011, *available at* 

http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4192&intNumPerPage=10&checkDate=&checkKey=&srch Type=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year =&desc=&cboOrder=date (last viewed Nov. 30, 2011).

<sup>&</sup>lt;sup>9</sup> Id. <sup>10</sup> Id.

<sup>&</sup>lt;sup>11</sup> Id.

<sup>12</sup> Centers for Medicare & Medicaid Services, "Medicare Expanding Competitive Bidding Program to Save Billions -Expanded by Affordable Care Act," Nov. Program 30, 2011, available at http://www.cms.gov/apps/media/press/release.asp?Counter=4191&intNumPerPage=10&checkDate=&checkKey=&srchTy pe=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPag e=&showAll=&pYear=&year=&desc=&cboOrder=date (last viewed Nov. 30, 2011).

<sup>&</sup>lt;sup>13</sup> Centers for Medicare & Medicaid Services, "Medicare Announces Timeline, Starts Bidder Education for Durable Medical Equipment, Prosthetics, Orthotics and Supplies – Competitive Bidding Program Round 2 and National Mail-Order Competitions," Nov. 30, 2011, available at <a href="http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4192&intNumPerPage=10&checkDate=&checkKey=&srch">http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4192&intNumPerPage=10&checkDate=&checkKey=&srch</a> Type=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year =&desc=&cboOrder=date
(last viewed Nov. 30, 2011).

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improved Request for Bids instructions, updated fact sheets, and a series of educational websites."<sup>15</sup> Additionally, there will be a toll-free helpline (1-877-577-5331) for assistance with bidding questions and concerns.<sup>16</sup> Suppliers also should ensure that they are on the appropriate listserves, as CMS often sends important information related to the bidding process via these channels.<sup>17</sup>

#### Mixed Reactions to Competitive Bidding

The Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act.<sup>18</sup> The Program involves DMEPOS suppliers submitting bids in order to become Medicare contract suppliers and to provide specific medical equipment and supplies in designated competitive bidding areas ("CBAs").<sup>19</sup> New payment amounts are determined based on the submitted bids, and subsequently replace the Medicare DMEPOS fee schedule amounts for bid items in the CBAs.<sup>20</sup> Round 1 of the Program was implemented for a brief two-week period in July 2008, before legislation delayed the Program.<sup>21</sup> Ultimately, a Round 1 Rebid was conducted and pricing implemented on January 1, 2011, in nine CBAs: 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 – Pompano Beach (Florida); Orlando (Florida); Pittsburgh (Pennsylvania); and Riverside - San Bernardino – Ontario (California).<sup>22</sup> The product categories for the Round 1 Rebid included the following: oxygen supplies and equipment; standard power wheelchairs, scooters, and related accessories; complex rehabilitative power wheelchairs and related accessories (Group 2); mail-order diabetic supplies; enteral nutrients, equipment, and supplies; CPAP, RADs, and related supplies and accessories; hospital beds and related accessories; walkers and related accessories; and support surfaces (Group 2 mattresses and overlays) in Miami.<sup>23</sup>

A CMS press release reports that "[t]o date, Round One of competitive bidding has yielded savings of 35% compared to the fee schedule, 51% of contracts [were] awarded to small businesses ... . Inquiries in the first quarter of 2011 totaled less than 0.9% of calls to the Medicare call center, *and* 

<sup>17</sup> Suppliers can sign up for these announcements on the CBIC website: <u>http://www.dmecompetitivebid.com</u>.
 <sup>18</sup> Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Overview," *available at* <u>https://www.cms.gov/DMEPOSCompetitiveBid/01\_overview.asp#TopOfPage</u> (last viewed Sept. 15, 2011).

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> Centers for Medicare & Medicaid Services, "Medicare Expanding Competitive Bidding Program to Save Billions – Program Expanded by Affordable Care Act," Nov. 30, 2011, *available at* <u>http://www.cms.gov/apps/media/press/release.asp?Counter=4191&intNumPerPage=10&checkDate=&checkKey=&srchTy</u> <u>pe=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPag</u> <u>e=&showAll=&pYear=&year=&desc=&cboOrder=date</u> (last viewed Nov. 30, 2011).

<sup>&</sup>lt;sup>19</sup> Centers for Medicare & Medicaid Services, "The Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Fact Sheet," *available at* https://www.cms.gov/MLNProducts/.../DMEPOSCompBidProg.pdf (last viewed Nov. 16, 2011).

<sup>&</sup>lt;sup>20</sup> Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Overview," *available at* <u>https://www.cms.gov/DMEPOSCompetitiveBid/01\_overview.asp#TopOfPage</u> (last viewed Sept. 15, 2011).

<sup>&</sup>lt;sup>22</sup>Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Metropolitan Statistical Areas, Competitive Bidding Areas, and Zip Codes," *available at <u>https://www.cms.gov/DMEPOSCompetitiveBid/01a\_MSAs\_and\_CBAs.asp</u> (last viewed Sept. 15, 2011).* 

<sup>&</sup>lt;sup>23</sup> Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Product Categories, Items, and HCPCS," *available at <u>https://www.cms.gov/DMEPOSCompetitiveBid/01b\_Product\_Categories\_and\_Items.asp#TopOfPage</u> (last viewed Sept. 15, 2011).* 

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*Medicare received only 45 complaints during that time*."<sup>24</sup> While current CMS Administrator Donald Berwick has said that the Program "will save Medicare, seniors and taxpayers \$28 billion over 10 years,"<sup>25</sup> several economic groups have stated that the Program will, in fact, lead to higher, rather than lower, health care costs.<sup>26</sup> At present, DMEPOS suppliers that are awarded contracts have a choice of accepting or rejecting contract bids. However, representatives from certain economic groups are arguing that suppliers should be required to accept a contract once they have made a bid, thereby removing the risk of price suppression by not allowing low bidders to simply walk away.<sup>27</sup> Additionally, CMS has stated that there have been no changes in beneficiary health status in the nine Round 1 Rebid CBAs, but critics of the Program have been quick to point out that this assertion is based on a very short time period and that the long-term impact of the Program is more important to consider.<sup>28</sup>

#### National Mail-Order Competitive Bidding Program for Diabetic Testing Supplies

At the same time as the Round 2 competition takes place, CMS also will conduct a national mailorder competitive bidding program for diabetic testing supplies. The national mail-order CBA includes all ZIP codes throughout the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. As noted above, CMS recently released a timeline that is applicable to both Round 2 and the national mail-order competition.

According to CMS, Medicare beneficiaries who "permanently reside" in a mail-order CBA will be able to purchase their diabetic supplies from a winning mail-order contract supplier ("Contract Supplier") for the area in which the beneficiary resides or from a non-Contract Supplier in cases where the supplies are not furnished on a mail-order basis. CMS has said, "It is solely up to beneficiaries to decide whether or not they wish to obtain their diabetic testing supplies on a mail-order basis."<sup>29</sup> Contract Suppliers will be required to make available the same range of products to Medicare beneficiaries that they make available to non-Medicare customers. Medicare Part B payment will not be made to non-Contract Suppliers that furnish mail-order diabetic testing supplies to Medicare beneficiaries residing in a CBA. However, non-Contract Suppliers that furnish non-mail-order diabetic testing supplies will be reimbursed at the fee schedule amount for the state where the beneficiary maintains a permanent residence.<sup>30</sup> Additionally, Medicare Part B payments can be made for provision of mail-order diabetic supplies by non-Contract Suppliers that furnish such supplies to Medicare beneficiaries who do not reside in a CBA.<sup>31</sup>

<sup>&</sup>lt;sup>24</sup> Centers for Medicare & Medicaid Services, "Medicare to Save Taxpayers and Beneficiaries \$28 Billion with an Expanded Competitive Bidding Program: Program to Purchase Durable Medical Equipment Beginning Second Phase," Aug. 19, 2011, available at <a href="https://www.cms.gov/apps/media/press/release.asp?Counter=4064&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date">https://www.cms.gov/apps/media/press/release.asp?Counter=4064&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date">https://www.cms.gov/apps/media/press/release.asp?Counter=4064&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date"</a> (emphasis added).

<sup>&</sup>lt;sup>26</sup> BNA, "Economic Groups Say DME Bidding Program Will Inevitably Result in Higher Health Costs," Aug. 23, 2011. <sup>27</sup> *Id.* 

<sup>&</sup>lt;sup>28</sup> Id.

<sup>&</sup>lt;sup>29</sup> Centers for Medicare & Medicaid Services, "The Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program Mail-Order Diabetic Supplies Fact Sheet" (Nov. 2010), *available at* <u>http://www.cms.gov/MLNProducts/downloads/DME\_Mail\_Order\_Factsheet\_ICN900924.pdf</u> (last viewed Sept. 19, 2011). <sup>30</sup> *Id.* The "permanent residence" is the beneficiary's address on file with the Social Security Administration.

<sup>&</sup>lt;sup>31</sup> *Id*.

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The idea of a national mail-order program for diabetic testing supplies has been a topic of much discussion since at least 2006, when CMS requested comments on such a program. In the April 2007 final rule for the Program, CMS responded to the comments submitted regarding a national mail-order program, stating that over 60 percent of Medicare expenditures for diabetic supplies are for items furnished by nationwide mail-order suppliers, as well as clarifying that a national mail-order program, if implemented, would not be mandatory for beneficiaries.<sup>32</sup> In July 2010, CMS proposed a rule to establish a national mail-order program that would take place after 2010. In the proposed rule, CMS outlined three new requirements: (1) a new definition of what constitutes "mail order"; (2) a rule that would require contract suppliers to provide, at a minimum, 50 percent of all of the different types of diabetic testing products on the market by brand and model name (also known as the "50 Percent Rule"); and (3) a prohibition against influencing and incentivizing beneficiaries to switch their brand of monitor and testing supplies (also known as the "Anti-Switching Rule").<sup>33</sup> After consideration of the public comments, CMS finalized the proposed rule in November 2010 without modification.<sup>34</sup>

# What Should DMEPOS Suppliers Do to Prepare for Round 2 and the National Mail-Order Program?

Despite industry criticism and opposition to the Program, interested DMEPOS suppliers need to be ready for this next bidding phase. Suppliers that are interested in bidding should update their contact information or enrollment files (including names, Social Security numbers, and dates of birth for all Authorized Officials, as well as a current address for correspondence) with the National Supplier Clearinghouse ("NSC").<sup>35</sup> Supplier files that are not current with the NSC will lead to delays and suppliers may risk not being able to register and bid for contracts.<sup>36</sup> Additionally, DMEPOS suppliers must obtain all required state licenses for each product category that they are interested in bidding for, as contracts are awarded only to suppliers that possess the required licenses.<sup>37</sup> The licenses must be on file with the NSC before bids are submitted, and every location must be licensed in each state in which services are provided.<sup>38</sup> These licensure requirements are extremely important, as bids will be rejected if licenses are expired or missing from supplier enrollment files.<sup>39</sup> Finally, DMEPOS suppliers must be accredited by a CMS-approved accreditation organization for all items in a particular product category in order to place a bid for that category.<sup>40</sup>

Additional information regarding Round 2, the national mail-order program, and the Program generally can be found on both the CMS and CBIC websites.

https://www.cms.gov/DMEPOSCompetitiveBid/01A1\_Announcements\_and\_Communications.asp#TopOfPage.<sup>36</sup> *Id.* 

<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>39</sup> Id.

<sup>40</sup> *Id*.

<sup>&</sup>lt;sup>32</sup> 72 Fed. Reg. 17992, 18018-18019 (Apr. 10, 2007).

<sup>&</sup>lt;sup>33</sup> 75 Fed. Reg. 40040, 40211-40215 (July 13, 2010).

<sup>&</sup>lt;sup>34</sup> 75 Fed. Reg. 73170, 73567-73574 (Nov. 29, 2010).

<sup>&</sup>lt;sup>35</sup> Centers for Medicare & Medicaid Services, "DMEPOS Competitive Bidding Program Expansion Announced," Aug. 19, available
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#### Legislative Inquiry Related to Fraud and Abuse Enforcement Actions

The Affordable Care Act ("ACA") gave the Secretary of Health and Human Services ("HHS") the authority to impose temporary moratoria on the enrollment of new Medicare, Medicaid, or Children's Health Insurance Program (also known as "CHIP") providers and suppliers, or categories of providers and suppliers, if it is determined that such a suspension of enrollment is necessary in order to prevent or combat fraud, waste, or abuse within the health care system.<sup>41</sup>

Last month, Senators Orrin Hatch (R-Utah) and Charles Grassley (R-Iowa) sent a letter to Kathleen Sebelius, Secretary of HHS, asking for an explanation as to why CMS has yet to impose temporary moratoria on the enrollment of new providers and suppliers where there is high risk of, or potential for, fraud (the "Hatch-Grassley Letter").<sup>42</sup> The Hatch-Grassley Letter stated that:

[M]ore than a year after the publication of a proposed rule and more than 8 months after publishing the aforementioned final rule with comment, CMS has still not imposed a single temporary moratorium. In addition, despite a specific recommendation by the HHS Office of the Inspector General ("HHS-OIG") to impose a temporary moratorium on independent diagnostic testing facilities in Los Angeles, California, CMS refused.<sup>43</sup>

The Hatch-Grassley Letter also identified certain geographic areas that have "historically been vulnerable to Medicare fraud and are high risk areas for programmatic vulnerability." These areas include cities in California, Florida (and, in particular, Miami), Illinois, Louisiana, Michigan, New York, and Texas (the "Strike Force Cities").<sup>44</sup>

The Hatch-Grassley Letter requested a significant amount of information from Secretary Sebelius, including an explanation of the steps that CMS is taking to address concerns raised by HHS-OIG related to the testing facilities in Los Angeles. Other information requested included an explanation as to why a temporary moratorium has not been imposed with respect to "high" or "moderate" categorical risk providers and suppliers in the Strike Force Cities, or other high-risk areas, and facts related to CMS's decision to not impose a moratorium on DMEPOS suppliers in South Florida. Additionally, the Secretary was asked to describe the changes that CMS is contemplating in order to strengthen the provider enrollment process for "moderate" and "high" screening risk providers and suppliers, and to provide information related to certain providers, suppliers, and Medicaid programs (*e.g.,* a list of the provider and supplier types with a highly disproportionate number of providers and suppliers relative to the number of beneficiaries for each state, and a list of state Medicaid programs that have imposed moratoria on a group of Medicaid providers or suppliers that also are eligible to enroll in Medicare).<sup>45</sup>

<sup>&</sup>lt;sup>41</sup> Refer to Epstein Becker Green's *Implementing Health and Insurance Reform* alert "New Regulations Implement Health Reform's Enforcement Tools: Providers and Suppliers in Focus," *available at* <u>http://www.ebglaw.com/showclientalert.aspx?Show=13994</u> (Feb. 14, 2011).

<sup>&</sup>lt;sup>42</sup> Letter to Kathleen Sebelius from Senators Orrin Hatch and Charles Grassley (Oct. 25, 2011).

<sup>&</sup>lt;sup>43</sup> *Id*.

<sup>&</sup>lt;sup>44</sup> Id.

<sup>&</sup>lt;sup>45</sup> *Id*.

#### Key Considerations

Providers and suppliers face a brave new world of Medicare and Medicaid enrollment screening and enforcement. As such, they need to be aware of the heightened attention to these initiatives. These efforts by CMS are just one example of the federal government's intention to increase the use of enforcement tools in order to combat fraud and abuse. Providers and suppliers need to develop proactive measures (*e.g.*, compliance programs, internal audits, data mining, frequent checks of the OIG and General Services Administration exclusion databases, and reviews of state license and registration databases to ensure good standing) to prepare for these levels of enforcement and the use of new tools to force health care organizations out of the federal health care programs through payment suspension when CMS determines, using its broad and largely undefined discretion, that a "credible allegation of fraud exists."<sup>46</sup>

Additional information regarding government efforts to stop health care fraud can be found at <u>http://www.stopmedicarefraud.gov</u>.

#### CMS to Implement Automated Pre-Enrollment Provider Screening

Another example of the government's intention and authority to use enforcement tools to combat fraud and abuse is CMS's recent announcement of plans to debut a provider/supplier enrollment screening system in <u>January 2012</u> that will automate its pre-enrollment risk assessment and screening processes. Pre-enrollment screening of providers and suppliers is considered an essential step in the government's efforts to fight fraud and abuse in the Medicare program. A more rigorous screening process will allow the agency to have greater control over the outflow of Medicare dollars.

According to CMS, the new system will help the agency identify potential risks of fraud and will reduce enrollment application times. It also will allow for continuous monitoring of enrollment related data (*e.g.*, Social Security death files).<sup>47</sup> CMS has awarded a \$41 million contract to Turning Point Global Solutions, Inc. ("TPGSI"), a Maryland-based software services company, to develop the screening system.<sup>48</sup> Significantly, CMS intends to use this relationship to compile provider-related data needed to support the National Fraud Prevention Program.<sup>49</sup> Additionally, TPGSI will assist CMS

<sup>&</sup>lt;sup>46</sup> 76 Fed. Reg. 5862 (Feb. 2, 2011).

<sup>&</sup>lt;sup>47</sup> BNA, "CMS to Roll Out Automated Pre-Enrollment Provider Screening in January, Official Says," Nov. 10, 2011.

<sup>&</sup>lt;sup>48</sup> See <u>http://www.tpgsi.com/index.html</u> (last viewed Nov. 15, 2011). TPGSI is a software engineering and information technology professional services firm. In the government sector, TPGSI customers include the VA, FEMA, CMS, FDA, CPSC, DoD, NTSB, DHS ICE, and DOT. The company helps federal agencies expedite technology upgrades and/or contract transitions, proactively manage telecom and network assets, implement enterprise level governance, and improve business processes. Prior to this September 30th award, TPGSI was awarded several other CMS contracts: (1) to enhance the information available for public reporting on the Physicians and Other Healthcare Professionals Directory ("PHPD") located on the CMS Medicare.gov website (Apr. 2011), and (2) to provide technology upgrades and maintenance support for the OIG Hotline Database and the Incentive Reward Program Database (June 2011). See <a href="http://www.tpgsi.com/news/pecos press release.html">http://www.tpgsi.com/news/pecos press release.html</a> and <a href="http://www.tpgsi.com/news/cms\_oig\_hotline.html">http://www.tpgsi.com/news/cms\_oig\_hotline.html</a> (last viewed Nov. 15, 2011).

<sup>&</sup>lt;sup>49</sup> CMS's Center for Program Integrity ("CPI") integrates similar functions from the Medicare and Medicaid programs to improve intra-agency coordination and deployment of resources to address health care fraud, waste, and abuse. CPI implemented the National Fraud Prevention Program ("NFPP") to reverse the traditional "pay and chase" approach to program integrity and instead focus on prevention and detection that is integrated, risk-based, and measurable. One of the main goals of the NFPP is to incorporate innovative technologies in integrated solutions. See https://www.cms.gov/CMSLeadership/30 Office CPI.asp#TopOfPage (last viewed Nov. 23, 2011).

in complying with additional screening requirements provisions mandated by ACA and implemented by CMS in March 2011, to automate the provider/supplier screening processes and to automate preenrollment assessments of risk.<sup>50</sup>

#### What Should Providers and Suppliers Do?

As CMS moves toward launching this automated enrollment system, providers and suppliers should monitor the agency's progress to understand how data requirements may change (in terms of what providers and suppliers will need to provide during the enrollment process), how the timing for the processing of enrollment applications will change, and how CMS ultimately decides to use the data collected to pursue allegations of fraud and abuse.

Information regarding the Hatch-Grassley Letter can be found at <u>http://finance.senate.gov</u>.

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For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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