The Honorable Orrin Hatch  
Senate Finance Committee  
United States Senate  
Washington, DC 20510  

Dear Senator Hatch:

Thank you for your letter regarding the Centers for Medicare & Medicaid Services’ (CMS) oversight of providers operating in Medicare’s traditional fee-for-service program. We appreciate your interest in our program integrity efforts and are pleased to have the opportunity to report on the significant progress we have made in the last 18 months to address your concerns.

CMS has taken a new approach to address fraud, waste and abuse in the Medicare and Medicaid programs. The first strategic action was the creation of the Center for Program Integrity (CPI) in April 2010, which consolidated the Medicare and Medicaid program integrity groups under one management structure. This change strengthened and coordinated existing and planned fraud, waste and abuse activities. In February 2011, CPI realigned into five functional groups: Data Analytics, Provider Enrollment, Program Integrity Enforcement, as well as the Medicaid and Medicare Program Integrity Groups. This targeted approach has enabled CMS to pursue a more strategic and integrated set of program integrity policies and activities across Medicare, Medicaid, and Children’s Health Insurance Programs.

Since then, CPI has implemented a number of innovations to modernize the Agency’s anti-fraud and abuse efforts. For example, CPI implemented a new predictive analytic technology that is based on proven technology that has demonstrated effectiveness in reducing fraud losses by several orders of magnitude in the private sector, while reducing required operational resources by more than half. This technology, the Fraud Prevention System (FPS), is now screening all Medicare fee-for-service claims using sophisticated algorithms and models to identify suspicious behavior before claims are paid. Importantly, the FPS is also a resource management tool: the system automatically sets priorities for our program integrity contractors’ workload to focus CMS resources on the highest risk situations that demand immediate attention and response.

We are also integrating advanced analytic techniques into provider enrollment. CMS has awarded a contract for an automated provider enrollment screening process that will address many of the concerns raised in your letter, as described below. In addition, CMS is modernizing the provider enrollment Web site, Provider Enrollment Chain and Ownership System (PECOS).
By modernizing the enrollment process, we are reducing the burden on legitimate providers while making it easier to identify bad actors whose sole intent is to defraud the Medicare program. Enclosed is information that responds to your request and questions. I will also provide a copy to the cosigner of your letter.

Sincerely,

Donald M. Berwick, M.D.

Enclosure
Response to September 27, 2011 Questions

1. CMS Oversight and Implementation of Surety Bond Requirement for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) suppliers.

**Response:** Section 1834(a) of the Social Security Act, as amended by section 4312(a) of the Balanced Budget Act of 1997 (P.L. 105-33) requires DMEPOS suppliers provide a surety bond of not less than $50,000 as a condition of enrollment, or face denial or revocation from the program. CMS published the final rule (74 FR 166) implementing this requirement on January 2, 2009, and the requirement became effective on October 2, 2009.

In order to implement the requirement properly, CMS spent 2009 and early 2010:
- Conducting significant outreach and education on the new requirements;
- Answering inquiries from the DMEPOS supplier community;
- Developing an extensive list of “Frequently Asked Questions” (accessible at www.palmettobga.com/nsc) to address various policy issues, such as: (1) the specific factual situations to which the surety bond exceptions apply, and (2) how and under what circumstances suppliers should submit surety bonds; and
- Drafting and issuing formal sub-regulatory guidance.

Surety bonds are currently required for enrollment and are to be collected and applied to any Medicare overpayments found by our contractors. CMS has developed draft final guidance to be used in managing the collection of overpayments and other uncollected debt through the surety bond. The operational issues associated with surety bond collection are broad and complex, and we are continuing to work toward finalizing the procedures.

a. **Provide copies of all draft and final instructions; technical direction issued to CMS contractors regarding identification and collection of DMEPOS overpayments.**

**Response:** As a general legal matter, CMS does not disclose or release drafts of policy documents, such as the instructions you requested. We are able to provide you with links to all final documents.
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<thead>
<tr>
<th>DOCUMENT</th>
<th>LINK</th>
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b. Provide copies of all draft and final instructions; technical direction issued to CMS contractors regarding enforcement of the DMEPOS surety bond requirement related to enrollment of new and existing providers.

Response: As stated above, the final instructions and technical direction related to the collection against a surety bond are still under development. As a general legal matter, CMS does not disclose or release drafts of policy documents, such as the instructions you requested.

However, we are able to provide the final guidance to the contractors for the enforcement of the surety bond as an enrollment requirement.
c. Request for the number of DMEPOS suppliers currently enrolled in the Medicare program as of 1/1/2010; 1/1/2011; and 10/1/2011.

Response: In order to provide a clearer picture of the DMEPOS landscape, we are also providing the number of DMEPOS suppliers enrolled as of April 2006 and January 2009.

<table>
<thead>
<tr>
<th>DATE</th>
<th>DMEPOS SUPPLIERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/03/2006</td>
<td>118,473</td>
</tr>
<tr>
<td>01/01/2009</td>
<td>108,274</td>
</tr>
<tr>
<td>01/01/2010</td>
<td>97,164</td>
</tr>
<tr>
<td>01/01/2011</td>
<td>99,151</td>
</tr>
<tr>
<td>10/01/2011</td>
<td>102,325</td>
</tr>
</tbody>
</table>

The number of DMEPOS suppliers enrolled with the National Supplier Clearinghouse (NSC) has declined approximately 14 percent over the past six years. The most significant factor in this reduction can be attributed to the requirements to possess a surety bond and become accredited, both of which were implemented on October 1, 2009. Based upon those new requirements, 10,553 suppliers were revoked between October 2009 and December 1, 2009. Due to the large number of last minute filings, 2,803 of those revocations were subsequently overturned as the suppliers were able to demonstrate compliance with both requirements. In addition to those revoked, approximately 1,500 more suppliers voluntarily terminated their enrollment between September 1, 2009, and December 31, 2009. While the specific reasons cannot be determined, it is believed a significant number did so to avoid facing revocation actions until they
could procure a surety bond or obtain accreditation. Since the implementation of the surety bond and accreditation requirements, the number of enrolled DMEPOS suppliers has risen slightly.

2. **Request for information on whether CMS is taking appropriate action to revoke convicted or unlicensed providers from Medicare.**

   **Response:** CMS strongly agrees that the allowing of an unlicensed or Office of Inspector General or General Services Administration-excluded provider into the Medicare program is unacceptable. CMS is working to strengthen Medicare enrollment processes and systems to prevent fraudulent providers from enrolling in the program.

   One of the ways we are strengthening enrollment is through automated provider screening. CMS awarded a contract for automated provider screening on September 30, 2011, and full implementation is expected to begin by January 2012. The screening will occur upon initial enrollment and revalidation of an enrollment application. The enrollment screening process will automate the monitoring of all providers and suppliers to ensure they continue to meet Medicare enrollment requirements, such as State licensure, for the duration of their enrollment. The data sources used for this effort include the National Plan and Provider Enumeration Systems for the National Provider Identifier (NPI), the General Services Administration (GSA) Excluded Parties List System (EPLS), for parties excluded from receiving Federal contracts, and the Office of Inspector General (OIG) exclusion database, for providers and suppliers who are excluded from participation in any Federally-funded healthcare program.

   We expect continuous monitoring of databases will be an improvement over manual checks, and streamline the enrollment process. Legacy procedures required MACs to check certain databases manually, including State licensing boards and the EPLS maintained by GSA, which discloses individuals and entities that are barred from receiving Federal Government contracts, acting as subcontractors, and receiving certain other Federal benefits. In the past, CMS has mainly relied on self-disclosure of any changes in information, including the reporting of any criminal convictions or plea agreements. However, providers in the PECOS database are systematically checked against OIG’s Medicare Exclusion Database (MED), which identifies individuals and entities that are excluded from participating in Federal health care programs, on a monthly basis to identify any providers that may have been excluded during their enrollment with Medicare. The MACs also check the EPLS described above against information on the enrollment application during revalidation. These checks are required as MACs must verify all information on a Medicare application, including whether the provider supplier, its owners or managers, are excluded or debarred from Medicare. The new screening tool will automate these processes and streamline the contractors’ workload.
While the Agency has broad discretion to revoke for certain felony convictions, OIG is mandated by statute to exclude individuals or entities convicted of certain offenses, including both misdemeanors and felonies, but has no authority to exclude any person or entity convicted of offenses not specified by statute. OIG has discretion upon review of certain misdemeanor convictions to exclude, or not to exclude, the defendant from Federal health care programs. It is important to note that under existing statutory and regulatory authority, not all felonies are excludable offenses, such as a felony DUI or hunting violation. We believe that in many instances, this lack of even discretionary authority to exclude for such violations is the reason that some of the individuals listed in the table provided in the letter are still enrolled in the Medicare program. CMS has provided an overview of our findings below, as requested.

a. Investigate providers on list and send report on findings.

Response: CMS reviewed each of the lists provided in the September 27, 2011 letter. CMS’ findings are summarized below. CMS is unable to provide information on individual-level data due to Privacy Act requirements.

Table 1: Summary of physicians and non-physician practitioners with felony convictions or guilty plea who have retained their Medicare billing privileges and/or the ability to order and refer in the Medicare program as of September 19, 2011.

There were a total of 34 physicians and non-physician practitioners identified on the list provided in the September 27, 2011, letter. The table below summarizes our findings, and the variety of reasons these providers may have retained their Medicare billing privileges.

<table>
<thead>
<tr>
<th>Finding Description</th>
<th>No. of Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not have an approved PECOS enrollment record$^{1,2}$</td>
<td>7</td>
</tr>
<tr>
<td>Pending with OIG Exclusion Staff for possible exclusion</td>
<td>1</td>
</tr>
<tr>
<td>No exclusion potential at this time$^{3,5}$</td>
<td>8</td>
</tr>
<tr>
<td>Convictions are not excludable$^{4,5}$</td>
<td>13</td>
</tr>
<tr>
<td>No record of conviction in OIG systems$^{5}$</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34</strong></td>
</tr>
</tbody>
</table>

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1 One (1) individual was incorrectly identified on the chart.
2 Two (2) individuals were recently added to the MED Exclusion List.
3 Like other law enforcement agencies, the OIG can neither confirm nor deny the existence of a criminal investigation. In cases where a criminal investigation is ongoing, persons or entities may have been identified by the OIG as potential subjects of exclusion. Until that determination is made, however, the OIG cannot provide information which would reveal or disclose the existence or non-existence of the investigative process.
4 Based on the conviction information provided, the OIG determined that the felonies are not excludable offenses.
CMS will proactively screen and monitor these physicians and non-physician practitioners using the new automated provider screening tool once it has been implemented in January 2012. For example, the tool will provide notification alerts for any critical information changes such as licensure and felony convictions.

Table 2: Summary of physicians and non-physician practitioners with felony convictions or guilty plea that may be enrolled in the Medicare program, but who are not shown in the Medicare provider enrollment ordering and referring report.

There were a total of 41 physicians and non-physician practitioners identified on the chart. CMS' findings are summarized below.

- CMS confirmed that 38 physicians and non-physician practitioners do not have an approved enrollment record.
- The remaining three (3) physicians and non-physician practitioners do have an approved enrollment record. However, these three individuals all had conviction/plea agreement dates within the last 6 months. OIG will continue to monitor these cases to determine whether there is a potential for exclusion. In addition, CMS will proactively screen and monitor these physicians and non-physician practitioners using the new automated provider screening tool once it has been implemented in January 2012. For example, the tool will provide notification alerts for any critical information changes such as licensure and felony convictions.

Table 3: Summary of health care entity owners with felony convictions or guilty pleas who may have retained their Medicare billing privileges.

There were a total of 14 health care entity owners with felony convictions or guilty pleas identified on the chart. CMS' findings are summarized below.

- Eleven did not have an enrollment record
  - For one of the eleven, CMS identified multiple individuals with the same name; however, none were listed as owners for any organization in PECOS.
- One individual had an enrollment record with a “rejected” status.
- Two individuals have an enrollment record with an “approval recommended” status; at this point in the review process, the application is forwarded to the applicable State agency and RO that will be handling the survey and certification process from that point forward. CMS will proactively screen and monitor these physicians and non-physician practitioners using the new automated provider
screening tool once it has been implemented in January 2012. For example, the tool will provide notification alerts for any critical information changes such as licensure and felony convictions.

b. Provide copy of any interagency agreement, including performance measures, between CMS and DOJ, IRS, OIG and State officials regarding alerting CMS of felony indictments and/or convictions.

Response: CMS and DOJ, IRS, OIG and State officials do not have interagency agreements or performance metrics in place for the sharing of felony indictment or conviction information. As noted above, CMS and OIG have independent, discretionary authority to remove individuals from Medicare for certain criminal convictions. CMS and our contractors have traditionally relied on the exclusions of the OIG, as recorded in the MED database. Our contractors check the MED as part of an initial application or revalidation request. In addition, providers in the PECOS database are systematically checked against the MED file on a monthly basis to identify any providers that may have been excluded during their enrollment with Medicare.

c. Explain what actions CMS takes after DOJ obtains conviction for health care fraud.

Response: As noted above, for specific actions, CMS relies on the MED list for Medicare-relevant convictions. To identify and address systemic program issues, CMS is developing a Program Vulnerability Tracking System (PVTS) which will inventory and prioritize vulnerabilities identified by internal sources: MACs, Recovery Audit Contractors, Zone Program Integrity Contractors, Medicare Drug Integrity Contractors, the new predictive analytic contract, the new provider screening contract and other sources such as Comprehensive Error Rate Testing Reports, OIG Reports, and the General Accounting Office (GAO) reports.

d. Provide copy of procedures used by CMS to notify contracted Medicare Advantage Organizations (MAO).

Response: MAOs are required to have procedures in place to ensure they do not employ or contract with excluded providers. CMS has provided sub-regulatory guidance to MAOs instructing them to check the OIG and GSA excluded provider lists regularly to ensure compliance.
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<thead>
<tr>
<th>DOCUMENT</th>
<th>LINK</th>
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<tbody>
<tr>
<td>Medicare Managed Care Manual, Chapter 6-Relationships With Providers</td>
<td><a href="https://www.cms.gov/manuals/downloads/me86c06.pdf">https://www.cms.gov/manuals/downloads/me86c06.pdf</a></td>
</tr>
</tbody>
</table>

CMS does not have formal procedures to notify MAOs when a physician or non-physician practitioner or health care entity’s Medicare billing privileges are revoked, and there are no provisions in the MAO contract requiring them to check on the enrollment status of providers.

**Explain CMS oversight of contractor action on revoked or suspended medical licenses.**

**Response:** CMS conducts ongoing onsite reviews of the contractors to ensure they are meeting the provider enrollment application processing requirements. In addition, the new automated provider screening will allow us to monitor all providers and suppliers automatically to ensure they continue to meet Medicare enrollment requirements, such as State licensure, throughout the duration of their enrollment. Contractors will be notified by CMS if a provider or supplier fails to meet the necessary enrollment requirements, and will be required to take action accordingly.

**e. Investigate and determine which contractors are not revoking Medicare billing privileges when a medical license is suspended or revoked; and take appropriate contract action to fix this deficiency.**

**Response:** CMS is implementing an automated screening contract to help address the challenge of continuously monitoring provider licensure status. The Medicare contractors currently check licensure status manually upon initial enrollment and during revalidation if the information is made available to the contractor by the State. In instances where the State does not provide the contractor with the licensure information, the provider is still required to submit documentation from the State board. With the implementation of the new automated screening process licensure status will become an automated verification activity that will be done on an ongoing basis in addition to the initial enrollment and revalidation processes.
Additionally, the OIG may exclude a provider or supplier for revocation of licensure, and the exclusion would be captured in the MED, against which PECOS systematically matches on a monthly basis.

f. Provide a list by contractor with the names of physicians/non-physicians with invalid State licenses continuing to participate in the Medicare and the administrative action/overpayment assessment for each.

Response: Any known unlicensed physicians and non-physician practitioners are removed from Medicare program upon discovery; therefore, CMS is unable to provide a list of individuals without valid licenses who are currently enrolled in the Medicare program.

3. Determine what providers are enrolled as “undefined” or “other” and continue to bill Medicare, and provide the name and location, whether a site visit was conducted prior to enrollment for each.

Response: CMS maintains an “other” category on the enrollment application to address providers or suppliers that may submit an enrollment application to Medicare, but whose provider type is not otherwise listed on the enrollment form. Due to the Privacy Act, CMS is unable to provide a list of individual providers or suppliers that are enrolled as “other” in Medicare.

4. Explain what action CMS takes to identify physicians disciplined by the State for documentation errors.

Response: The MACs review State licensing information monthly to determine if any practitioners, within the past 60 days, have had their license revoked, suspended, or otherwise inactivated. As noted above, CMS recognizes that there are significant challenges with obtaining licensure information in real-time for all Medicare provider and suppliers. With the implementation of the automated screening process licensure status will become an automated check that will be done on an ongoing basis in addition to the initial enrollment and revalidation processes.

5. Claim edits

a. Explain why CMS has not implemented systematic ordering and referring edits for HHA, DMEPOS, labs, and independent diagnostic facilities, and provide a timeline of when CMS will implement these edits.

Response: CMS issued an Interim Final Rule with Comment Period (IFC) on May 5, 2010, just weeks after passage of the Affordable Care Act (ACA), requiring that physicians who order and refer items and services be enrolled in Medicare. In the IFC, CMS required that all physicians and other eligible professionals must be enrolled in the PECOS, the current enrollment system, rather than requiring enrollment in Medicare – which would have encompassed
all of the legacy enrollment system as well. Upon initial implementation, CMS found that many providers and suppliers only had enrollment records in local systems at the MACs. As a result, there was a substantial backlog of applications and lengthy delays in processing new applications of providers and suppliers not yet in PECOS. To address provider concerns CMS delayed activation of the automated edits that would reject claims for services ordered or referred by physicians or other practitioners who were not enrolled in PECOS, as required in the IFC. We took this action to ensure that legitimate providers were not unduly denied payment due to the extended wait resulting from the backlog at the MACs. While CMS is not currently rejecting or denying claims for services ordered or referred by physicians or other practitioners who are not enrolled in Medicare, we have been providing informational messages to encourage providers and suppliers who have been submitting claims for such orders or referrals to enroll in PECOS.

b. **Estimate the cost to the program of forgoing the implementation of systematic ordering and referring edits on an annual basis.**

**Response:** We are unable to estimate the cost of forgoing the implementation.

c. **Estimate the impact on the CMS error rate of foregoing implementation of systematic ordering and referring edits on an annual basis.**

**Response:** We are unable to estimate the impact on the error rate.

d. **Explain why CMS has not implemented a provisional period of enhanced oversight for moderate/high providers, and provide a timeline for when CMS will implement these edits.**

**Response:** Section 6401(a) of the ACA gives CMS the authority to implement provisional period of enhanced oversight for new providers of services and suppliers, such as prepayment review and payment caps. CMS is developing the policy options for this provision, and is working to integrate it with other strategies, including the new screening requirements and the surety bond requirements. CMS is considering a number of options for implementation and has not determined the approach to be taken.

As mentioned above, CMS has also implemented a number of other activities that have enhanced the oversight of the Medicare program. These include site visits for all providers and suppliers in the moderate and high screening level, the provider/supplier profiles developed by the Fraud Prevention System, and the planned automated provider screening.
e. Estimate the amount of payments by provider type made to newly enrolling providers and suppliers in the moderate and high screening levels during FY 2011.

**Response:** CMS collects payment information by category of service, rather than provider or supplier type. Therefore, we are unable to provide estimates for the categories of providers and suppliers in the moderate category, but, because Home Health and DMEPOS are distinct service categories, we have supplied the estimates below.

<table>
<thead>
<tr>
<th>Service Category</th>
<th>FY2011 Estimate Part A</th>
<th>FY2011 Estimate Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMEPOS</td>
<td>NA</td>
<td>$8,279,000,000</td>
</tr>
<tr>
<td>Home Health</td>
<td>$7,069,000,000</td>
<td>$12,022,000,000</td>
</tr>
</tbody>
</table>

f. Explain why CMS suspended the practice of deactivation for 12 months of non-billing for Part B suppliers, if CMS consulted with OIG, the impact on identity theft, and whether physicians have complained to CMS.

**Response:** CMS has suspended the deactivation of Part B suppliers, except DMEPOS suppliers, for 12 months of non-billing beginning in early 2011 to minimize burden on the provider community. CMS has discretionary authority in its regulations on whether or not to deactivate, and CMS has chosen to act on that discretion. However, CMS may deactivate providers for non-billing on a case-by-case basis. For example, deactivation for non-billing would impact a pediatrician who is enrolled in Medicare, but who rarely treats Medicare patients. CMS believes the provider burden and workload reduction is significant, and recently proposed to permanently exempt a provider enrolled as an individual physician or non-physician practitioner in the recently released proposed rule “Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction” (CMS-9070-P). We estimated that an average of approximately 12,000 physicians and non-physicians are deactivated each year under this policy. These individuals are then required to complete a new enrollment application to reactivate their Medicare billing privileges. Eliminating the policy of deactivation for non-billing for these providers would result in a total estimated savings for affected physicians and non-physician practitioners of approximately $2.7 million per year. CMS also believes that individual providers and practitioners who are not billing do not pose an elevated risk to the Medicare program. During the internal regulation development process, the OIG had the opportunity to review and clear this policy proposal, and concurred with this change. CMS has issued guidance to its contractors to conduct certain verification activities to guard against physician and non-physician practitioner identity theft. CMS has not received any complaints from physicians, as this policy reduces burden directly on this provider type. In fact, the policy proposal received support during a stakeholder meeting in the fall of 2010, where
representatives of provider groups such as the American Medical Association, Medical Group Management Association, and the Association of American Medical Colleges identified deactivation for non-billing as a significant burden to physicians and their practices.

g. Explain whether CMS implemented a practice of deactivating privileges for Part A, and if this practice has been suspended.

Response: CMS has suspended the deactivation of Part A providers beginning in early 2011 to minimize burden on the provider community, for the reasons provided above.

h. Explain whether CMS implemented a practice of deactivating privileges for DMEPOS, and if this practice has been suspended.

Response: The process of deactivating DMEPOS for not billing in four consecutive quarters routinely occurred until July 2010. On October 2, 2010, all DMEPOS supplier enrollment data was moved from the NSC enrollment systems to PECOS. Based upon system limitations as a result of this migration, it was no longer possible to systematically deactivate non-billing suppliers until they had at least four consecutive quarters enrolled in PECOS. Now that DMEPOS suppliers have been enrolled in PECOS for four quarters, the systematic deactivations began again in November 2011.

6. Why is CMS implementing a one-size-fits-all approach to revalidation?

Response: We disagree with this characterization as the revalidation effort is being implemented in phases, and is based on a risk-minimization strategy. The first phase of revalidation is currently underway for providers that have outdated enrollment records, or are considered to pose an elevated risk to the Medicare program. This includes providers not yet enrolled in PECOS, and Home Health Agencies, Independent Diagnostic Testing Facilities and DMEPOS suppliers that have been flagged for suspect characteristics. In subsequent phases of the revalidation effort, providers and suppliers who have been identified through predictive modeling and automated screening activities will be systematically selected for immediate revalidation. Providers who pose a low risk of fraud will be revalidated in the latter phases of the effort. This approach will allow us to quickly identify and prevent fraudulent providers from continuing to bill, and also minimize the burden on physicians and non-physicians who comprise the largest number of those requiring revalidation. Far from implementing a one-size-fits-all approach to revalidation, this strategy is targeted to areas of the greatest vulnerabilities for CMS, and is an efficient use of Agency and contractor resources.