THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

October 23, 2009

The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510-6200

Dear Senator Grassley:

Thank you for your letter expressing concern with the Department of Health and Human Services' (HHS) responses to Management Implication Reports (MIRs) produced by the Office of the Inspector General (OIG) of HHS from 2006 to present. I would like to assure you that I view the OIG as a partner who helps HHS identify potential program vulnerabilities, particularly in the areas of Medicare and Medicaid.

You express concern that the absence of a formal written response to the MIRs provided by the OIG indicates that the recommendations in the reports did not receive appropriate consideration. However, while there may not have been written responses to the OIG, in a number of cases the Centers for Medicare & Medicaid Services (CMS) and other Departmental components implemented policy changes through revised regulations, strengthened payment and coverage policies, or clarified guidance to contractors based on the OIG recommendations. We would also note that in addition to considering the recommendations in the OIG's MIRs, CMS routinely responds, in a timely manner, to the formal reports developed by the OIG that identify systemic weaknesses or potential vulnerabilities in the Medicare and Medicaid programs. These reports have given CMS valuable information which it has utilized to strengthen and improve our overall program oversight efforts. Since 2006, CMS has responded to 362 draft and final reports from the OIG.

Nonetheless, I am not satisfied that existing policies across HHS for responding to OIG MIRs adequately ensure that the findings and recommendations contained in the reports receive sufficient and documented responses. My office is working directly with the OIG to improve the MIR process by implementing a thorough legal analysis of the MIRs prior to their issuance and requiring a written response by the relevant operating or staff division upon release of each MIR.

In the case of reports pertaining to CMS, we acknowledge that the absence of a formal process for receiving and responding to the OIG's MIRs may have created an erroneous perception that these reports did not receive adequate consideration. In order to be even more responsive, CMS is instituting a new process for tracking and responding to the MIRs. As the enclosed chart shows CMS has responded to 11 of the 21 MIRs identified in OIG memoranda. We note that those items which are annotated " response pending" does not mean that CMS has not potentially addressed the issue raised by the MIR but only that a formal written response has not yet been provided.

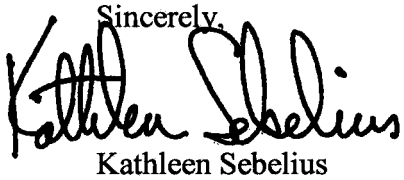
While we value the suggestions provided by the OIG through a variety of means, there will remain situations in which the Agency cannot fully adopt OIG's recommendations. This could be due to statutory or resource limitations, or competing priorities. A good example might be the OIG's recommendation that CMS mail beneficiary Explanation of Benefits (EOB) statements monthly rather than quarterly on a program-wide basis. While adopting such a recommendation would incur program management costs that CMS currently is not resourced to absorb, the Agency did incorporate this particular recommendation into an ongoing fraud demonstration in South Florida given the high risk for fraud in that area.

With resources limited and challenges great, CMS, OIG and all Departmental components will continue to work collaboratively and with our external partners – including those at the Department of Justice (DOJ) and the Federal Bureau of Investigations– to ensure the highest level of integrity in our public health care programs. Clamping down on fraud and abuse is among my highest priorities. That is why I am working directly with Attorney General Holder through the HEAT initiative to leverage scarce resources and root out fraud at the source with unprecedented prevention, detection, and enforcement techniques.

The initiative is having an impact. Recently, CMS and OIG entered into a Memorandum of Understanding to more quickly and efficiently institute payment suspensions against providers and suppliers suspected of fraudulent activity. By turning off the spigot at an earlier point in time, we are better safeguarding taxpayer dollars and freeing resources for more efficient fraud-fighting purposes than back-end recovery of improper payments. The Department and DOJ also have developed a strategy for expanding and improving the use and availability of data to combat health care fraud, particularly in fraud hot spots like the Strike Force locations. These are exciting strides in the fight against fraud, and I look forward to sharing more good news with you in the future.

Again, thank you for bringing this matter to my attention and for your steadfast commitment to integrity and efficiency in the Medicare and Medicaid programs. More detailed responses to some of your specific questions are included in the enclosure to this letter.

Sincerely,



Kathleen Sebelius

Enclosures

Supplemental Responses to Specific Questions

1) **Please explain what led to the problems described above and what will change to prevent them from happening in the future.**

   To prevent any future delays in responding to OIG's MIR recommendations, CMS is establishing a formal agency-wide process to track the MIRs and ensure that the Agency remains responsive to concerns expressed by the OIG. The Agency's Office of Strategic Operations and Regulatory Affairs in the Office of the Administrator will oversee this process so that all incoming MIRs and corresponding responses are coordinated through the Administrator's office.

2) **Please provide a timeline in which CMS will commit to adequately responding to all outstanding MIRs.**

   Please see the attached chart with the dates CMS responded to the OIG's MIR submissions. For those remaining MIRs awaiting response, we expect to have responses to the OIG no later than October 30, 2009.

3) **Please provide a commitment that CMS will adequately respond to all future MIRs within a 60-day timeline. If this timeline is not feasible, please explain why and to what timeline CMS will commit.**

   CMS is committed to responding within that timeframe.

ENCLOSURE

HHS MANAGEMENT IMPLICATION REPORTS
2009

PROGRAM	TITLE OF REPORT	DATE RECEIVED	STATUS	DATE RESPONDED TO OIG
FDA	Administrative and procedural violations and irregularities involving retention incentives awarded to various occupational specialities	April 15, 2009	Completed	October 6, 2009
OS	Administrative and procedural violations and irregularities in the religious compensatory time program at FDA and other departmental operating divisions	April 15, 2009	Response Pending – Working with operating divisions to resolve	
OS	Need for departmental security enhancements for IT assets	May 27, 2009	Response pending	
CMS	Durable Medical Equipment Providers Billing Medicare for Free Products (DPSE)	June 15, 2009	Response Pending	
CMS	Regulations Governing Nonemergency, Scheduled, Repetitive Ambulance Fraud	September 8, 2009	Response Pending	

HHS MANAGEMENT IMPLICATION REPORTS
2008

PROGRAM	TITLE OF REPORT	DATE RECEIVED	STATUS	DATE RESPONDED TO OIG
IHS	Lack of financial reporting requirements for IHS compactors	March 17, 2008	Completed	October 9, 2009
OS	Authority of senior managers to negotiate and bind the Department in contract matters and the potential appearance of conflict and/or impropriety in the use ofa contractor to perform inherently Government functions	March 21, 2008	Completed	October 9, 2009
CMS	Assigning Provider Numbers to Ineligible Foreign Nationals	July 31, 2008	Completed	October 29, 2008
CMS	Prevention of Unauthorized Withdrawals from Medicare Benefit Accounts	July 31, 2008	Response Pending	
CMS	Preventing Hit and Run Durable Medical Equipment Provider Fraud	August 29, 2008	Completed	January 8, 2009
CMS	Replacement Power Wheelchairs Related to Disaster Relief	September 3, 2008	Response Pending	
CMS	Lack of Data Transfer from a Former Program Safeguard Contractor to a New Program Safeguard Contractor	September 5, 2008	Completed	January 8, 2009

IHS	Property mismanagement	October 15, 2008	Completed	October 20, 2009
CMS	DME Claims Using Excluded Providers as the Referring Physicians	December 11, 2008	Completed	September 28, 2009
CMS	Unreliable and Incomplete Medicare Part D Claims Data	December 15, 2008	Response Pending	
CMS	Medically Unnecessary Drug Screening Tests	December 22, 2008	Completed	May 27, 2009
IHS	Exployment of excluded health care providers and other employees	December 22, 2008	Completed	October 9, 2009

HHS MANAGEMENT IMPLICATION REPORTS
2007

PROGRAM	TITLE OF REPORT	DATE RECEIVED	STATUS	DATE RESPONDED TO OIG
OS	Use of the HHS logo, in lieu of the HHS seal, on official Agency letterhead precludes criminal prosecution under 18 USC 506 & the current seal has not been posted to the Federal Register	January 17, 2007	Completed	October 9, 2009
CMS	Beneficiary Notification Prior to Medicare Provider/Supplier Payment	June 8, 2007 (1st Response) June 3, 2009 (2nd Response)	Completed Response to 1st MIR request Response Pending for 2nd MIR request	First Response – January 8, 2009
CMS	Medicare Part B – Medicare Allowing Payment of J-code Claims (Injectable Drugs) in Amounts That Are Not Medically Feasible	June 8, 2007	CMS has requested a copy of the MIR	
CMS	Misuse of the 79 Modifier	September 4, 2007	Completed	January 8, 2009
CMS	CPT Codes for Non-Chemotherapy Infusion Services	September 11, 2007	Completed	January 8, 2009
CMS	Limiting Drug Screens to Qualitative Testing	September 26, 2007	Completed	January 8, 2009
CMS	Improper Portable X-Ray Set-up and Transportation Payments	November 30, 2007	Response Pending	
CMS	Systemic Problems with Medicaid Managed Care Dental Services	November 30, 2007	Completed	July 16, 2009

HHS MANAGEMENT IMPLICATION REPORTS
2006

PROGRAM	TITLE OF REPORT 2006	DATE RECEIVED	STATUS	DATE RESPONDED TO OIG
CMS	Limitations on Units of CPT Code 80101 (Medicare Part B – Qualitative Drug Screening – No Limit to the Number of Units That Can Be Billed)	March 9, 2006	Response Pending	
CMS	Incident To Services	March 9, 2006	Response Pending	
CMS	Overutilization of Psychiatric Services in Nursing Homes	March 14, 2006	Response Pending	
CMS	Podiatrist's Fraudulent/Improper Use of Evaluation and Management Billing	March 14, 2006	Response Pending	
CMS	Physician License Suspension Notification	March 16, 2006	Response Pending	
CMS	Hemorrhoid Relief Centers	March 17, 2006	Response Pending	
CMS	Billing of Chemotherapy Drug Wastage	March 20, 2006	Response Pending	
CMS	Inappropriate Payment for Cardiac Rehabilitation Codes 93797 and 93798	May 1, 2006	Response Pending	
CMS	Medicare Part B – Co-management Among Opthmalogists and Optometrists	May 17, 2006	Response Pending	
CMS	Verification of Provider Knowledge of Medicare Regulations	May 19, 2006	Response Pending	

CMS	Regulation Change – 42 CFR 405.372 - Providers Being Criminally Investigated Allowed to Submit Claims and Receive Monies Held through Suspension before Criminal Matter is Resolved.	May 23, 2006	Completed	September 28, 2009
CMS	Nominee Owners of DME Companies	June 8, 2006	Response Pending	
CMS	Essential Claims Processing Data Missing from CMS' National Claims History File	July 5, 2006	Response Pending	
CMS	Lack of Adequate Physician Notification When Benefits Are Reassigned to New Provider and When Reassignments are Terminated	July 17, 2006	Response Pending	
CMS	Processing/Procedural Changes Needed for EDI and LCD with Respect to Therapeutic Footwear Claims	November 3, 2006	Response Pending	
CMS	Lack of Policies and Procedures Concerning the Handling and Distribution of Non-public Information	December 19, 2006	Response Pending	