

COMMITTEE ON FINANCE WASHINGTON, DC 20510-6200

October 16, 2009

Via Electronic Transmission

George W. Buckley Chairman, President and Chief Executive Officer 3M Company 3M Center St. Paul, MN 55144

Dear Mr. Buckley:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. As a senior member of the United States Senate and Ranking Member of the Committee, I have a special responsibility to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars authorized by Congress for these programs. This includes the responsibility to conduct oversight of the health care industry, including the manufacturers of Health Information Technology and Computer Physician Order Entry Systems (HIT/CPOE), for which about \$19 billion in taxpayer dollars has been earmarked for its development and implementation.

Over the past year, I have received complaints from patients, medical practitioners and technologies engineers regarding difficulties they have encountered with the HIT and CPOE devices in their medical facilities. These complaints include, for example, faulty software that miscalculated intracranial pressures and interchanged kilograms and pounds, resulting in incorrect medication dosages.

In addition, it has been reported that HIT/CPOE manufacturers rely on a legal doctrine known as "learned intermediaries," to shift responsibility for errors in the HIT systems to physicians, nurses, pharmacists, and other health care providers. The manufacturers allegedly argue that the health care provider should be able to identify and correct errors caused by the software. It has also been reported that HIT/CPOE contracts with medical facilities may include "hold harmless" provisions that absolve manufacturers of these products of any liability for errors that are allegedly HIT/CPOE system or software failures. These contracts may also include "gag orders," which prohibit health care providers from disclosing system flaws and software defects.

Furthermore, it was also reported to me that there is no system in place to track, monitor and report the performance of these systems/devices, which could impact a health care provider's ability to make informed decisions regarding the implementation of an HIT/CPOE system.

American taxpayers will be investing substantially in the HIT/CPOE industry, and it is important that their monies are appropriately spent on effective and interoperable HIT systems and devices. Accordingly, I would appreciate your response to the following questions and requests for information and documents by no later than November 6, 2009. Unless otherwise noted, the requests cover the period of January 1, 2007 through the date of this letter. In responding to this letter, please repeat the enumerated question and follow with the appropriate response and documentation.

- 1) Please provide a product list and description and function of all HIT/CPOE products manufactured and distributed by 3M Company (3M) and its subsidiaries.
- 2) Does 3M include language in its contracts that could be considered "Hold Harmless" provisions? If so, please provide a copy of sample contracts with such provisions.
- 3) Does 3M incorporate the "learned intermediaries" doctrine in the HIT/CPOE contract? If so, please provide a copy of sample contracts with such language.
- 4) Please describe 3M's role in ensuring that health care providers are adequately trained to use your products. Please also provide a copy of any and all training manuals, training schedules, and power point presentations that illustrate HIT/CPOE functionality and use.
- 5) Please provide a copy of communications, including but not limited to memoranda, letters, meeting minutes and notes, email and correspondence, regarding complaints and/or concerns from health care providers/professionals and other clients with the HIT/CPOE systems manufactured by 3M.
- 6) Does 3M have any system in place to track, catalogue or maintain complaints and/or concerns regarding 3M's HIT/CPOE products? If so, please describe that system in detail.
- 7) Does 3M offer health care facilities and/or providers any financial incentives for purchasing 3M's products, such as shares in the company or financial interests in a 3M product? If so, please describe the different types of incentives offered by 3M.
- 8) Has 3M executed any settlement agreements relating either directly or indirectly to its HIT/CPOE devices and products in the past 18 months. If no, so state. If yes, please state how many have been executed.

In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to your cooperation and assistance on this important matter. If you have any questions, please do not hesitate to contact Emilia DiSanto or Angela Choy at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131.

Sincerely,

Charles E. Grassley Ranking Member

Chuck Aradey

Attachment

GENERAL INSTRUCTIONS

- 1. The term "3M Company" means its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which "3M Company" entered into a partnership, joint venture or any other business agreement or arrangement.
- 2. In complying with this document request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. In addition, produce documents that you have a legal right to obtain, documents that you have a right to copy or have access to, and documents that you have placed in the temporary possession, custody, or control of any third party.
- 3. No documents, records, data or information requested by the Committee shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.
- 4. If the document request cannot be complied with in full, it shall be complied with to the extent possible, which shall include an explanation of why full compliance is not possible.
- 5. In complying with this document request, respond to each enumerated request by repeating the enumerated request and identifying the responsive document(s).
- 6. In the event that a document is withheld on the basis of privilege, provide the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
- 7. Each document produced shall be produced in a form that renders the document susceptible of copying.
- 8. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same document.
- 9. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, or control.
- 10. This request is continuing in nature. Any document, record, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon location or discovery subsequent thereto.
- 11. All documents shall be Bates stamped sequentially and produced sequentially.

GENERAL DEFINITIONS

- 1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to the following: memoranda, reports, statistical or analytical reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (E-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, discs, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disc, or videotape. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
- 2. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intraoffice and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

- 3. The terms "relate," "related," "relating," or "regarding" as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject, including but not limited to documents concerning the preparation of other documents.
- 4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The masculine includes the feminine and neuter genders to bring within the scope of this document request any information that might otherwise be construed to be outside its scope.
- 5. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, by document or otherwise, and whether face to face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise. Documents that typically reflect a "communication" include handwritten notes, telephone memoranda slips, daily appointment books and diaries, bills, checks, correspondence and memoranda, and includes all drafts of such documents.