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December 15, 2011

VIA ELECTRONIC MAIL
(OIRA_submission@omb.eop.gov)

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer
725 17th Street, NW
Washington, DC 20503

Re: **CMS 10417: Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget**

To Whom It May Concern:

Our client, Hoveround Corporation ("Hoveround") is a manufacturer and supplier of power wheelchairs and has been providing services to Medicare beneficiaries for nearly twenty years. We write regarding the recent request by the Centers for Medicare & Medicaid Services ("CMS") for the Office of Management and Budget's ("OMB's") emergency approval of a series of collection activities under the Paperwork Reduction Act ("PRA").[1]

Over the past decade, CMS has instituted a number of measures to restructure and address concerns about fraud in the Medicare power mobility device ("PMD") benefit, including (1) expanding the number of PMD billing codes from 4 to over 60; (2) developing national coverage policies and regulations calling for expensive physician and supplier prepared paperwork and other burdens; (3) developing local coverage policies with detailed documentation criteria; (4) including the benefit in the competitive bidding program; and (5) removing the beneficiary's purchase option and replacing it with a monthly-rental program. CMS also has implemented prepayment review initiatives in certain circumstances to review compliance with its policies, under which CMS withholds payment pending a lengthy review period and ultimately denies a percentage of PMD claims for purported deficiencies under its new technical paperwork requirements. Despite all of these very significant and burdensome measures, our experience shows that roughly 85 percent of the claims CMS *denies* for purported deficiencies under a prepayment review process are actually meritorious claims. ***Roughly 85***

[1] 76 Fed. Reg. 76737 (Dec. 8, 2011).

percent of these denials have been reversed by independent administrative law judges ("ALJs") under CMS's own appeals process.[2]

But despite this record, CMS is now asking OMB to approve, on an emergency basis without meaningful public participation, CMS's plan to radically expand its multiple measures and also impose a new prepayment system and a new "preauthorization" regime through a "demonstration project" covering approximately 43 percent of all PMDs sold in the United States. As explained below, this new administrative process threatens to dismantle a benefit critical to the most basic human needs for independent living (such as toileting, feeding, dressing, grooming and bathing). Rather than allow CMS to leap precipitously to yet another system with potentially enormous negative effects on beneficiaries, suppliers and physicians, we strongly urge OMB to deny this "emergency" request and require that CMS take a careful and rational look at what types of measures are actually practical and effective. Only after a full review with appropriate public comment should CMS be allowed to impose yet another administrative process for the PMD benefit.

There is no question that CMS has statutory authority to conduct experiments and demonstration projects. This authority is designed for limited projects, to establish "[i]ncentives for economy while maintaining or improving quality in the provision of health services."[3] But this authority cannot realistically be applied to such a vast percentage of the PMD market. This is essentially a rulemaking—not a "demonstration." Moreover, not only is the demonstration's twenty-five percent reduction in payment if preauthorization is not requested on a claim an arbitrary penalty, but also to exercise its "demonstration project" authority, CMS *must* first seek advice and recommendations from specialists on how to tailor the demonstration to meaningfully assess what it is attempting to accomplish.[4] It has not done so.

Almost all PMD suppliers have always been ready and willing to work with CMS to address any and all concerns about possible fraud. But this can and should be done carefully, not with year-end rushed "emergency" measures with potentially devastating effects across an entire benefit category. This is government decision-making at its worst. CMS should proceed carefully and after full public comment, on a properly designed and limited demonstration.

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[2] PMD suppliers operate in a system now where claims are routinely denied for inappropriate technical reasons, but are later reversed by the Department of Health and Human Services' ALJs. CMS's new prepayment and preauthorization proposal may well make it practically impossible for suppliers to survive long enough to effectively pursue reversals by ALJs.

[3] 42 U.S.C. § 1395b-1.

[4] 42 U.S.C. § 1395b-1(b).

I. CMS's REQUEST FOR EMERGENCY CLEARANCE APPROVAL VIOLATES THE PAPERWORK REDUCTION ACT BECAUSE, AMONG OTHER THINGS, THERE IS NO "EMERGENCY"

To implement the PRA, absent justified exceptions, OMB approves information collection activity requests only after there have been two opportunities for public comment, with a total time-line of 90 days following initial agency notice of proposed collection activity.[5] Here, CMS has provided the public with only 10 days to comment and is seeking approval by December 19th, which is 5 days after the comment period ends (including a week-end). To justify this request to short-circuit the normal PRA approval process, CMS must establish that it meets one of the narrow statutory exceptions showing that an emergency exists, which it has failed to do.

Emergency reviews can be granted if (1) the public harm is reasonably likely to result; (2) an unanticipated event has occurred; or (3) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.[6] None of these criteria are met.

When assessing the public harm exception, OMB guidance provides that imminence and likelihood of the stated public harm are to be considered.[7] CMS has attempted to justify its emergency clearance request for this new collection on the basis of public harm, stating that "[p]ublic harm is likely to ensue if the normal clearance procedures are followed" and "approval of this data collection is essential to ensuring that Medicare claims are paid properly, thus preventing improper payments."[8] But there has been no substantial recent event necessitating an immediate change without proper vetting. Nor has CMS cited any looming imminent future event now necessitating the triggering of across-the-board prepayment reviews. Instead, this "emergency" is a matter of administrative convenience—so that CMS need not take the inconvenient steps of requesting and meaningfully addressing the required public comment.

Further, CMS has never shown its proposed demonstration is a rational step to avoid the purported harm. The Agency has not weighed the consequences of its broad-brush approach or

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[5] Specifically, the PRA requires an agency to publish a 60-day notice in the Federal Register to solicit public comment on the proposed collection before submitting its request to OMB. Upon submitting the request to OMB, agencies must then place a second notice in the Federal Register informing the public that OMB approval is being sought and providing the public a 30-day public comment period. Finally, OMB has 60 days after receipt of the information request to make a determination. 5 C.F.R.§§ 1320.8(d)(1), 1320.10(a).

[6] 44 U.S.C. § 3507(j)(1). This provision also requires CMS to establish that the collection is needed prior to the expiration of the normal PRA timeframe and that it is essential to CMS's mission.

7 See Cass Sunstein, Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process, OMB Memorandum M-11-07 (December 9, 2010).

8 CMS, Emergency Justification Supporting Request for Emergency Clearance of the Paperwork Reduction Act Package for Medicare Fee-for-Service Early Review of Medical Records (CMS-10417).

the very-real possibility of falling short on resources required to ensure it is done effectively through Medicare contractors who historically have not been able to timely meet such responsibilities. Indeed, ensuring that this type of weighing proceeds is exactly why meaningful public comment is required.

Nor do we agree that the very high percentages of PMD payment errors cited by CMS reflect accurately the identified errors, given the high reversal rates of claims on appeal, among other things. Most critically, perhaps, other initiatives already in place are being employed to limit both the payment amounts for PMDs (*e.g.*, competitive bidding and elimination of a lump sum payment option in favor of a rental payment) and truly abusive or fraudulent conduct through investigations and prosecutions by the Office of Inspector General of the Department of Health and Human Services and other enforcement arms of the government.

In addition, the animating principle for emergency clearance is unforeseeability.[9] Here, CMS was well aware of its PRA obligations and there should have been no issue with its ability to comply in a timely manner with the PRA requirements.

Perhaps equally as critical, CMS appears to conflate the use of prepayment reviews as a Medicare program integrity tool with a new demonstration targeting a specific benefit under the PRA. This is impermissible. Any "substantive or material modification to a collection of information after such collection has been approved" requires a new submission to OMB for review and approval.[10] Although CMS has stated in its supporting materials that "this collection does not represent a change in policy or burden,"[11] this is misleading at best. The analysis of an information collection regarding general prepayment review should be distinguished from the information to be collected under the PMD demonstration. While there may be precedent for OMB approval of a collection of prepayment review generally, this should not extend to the request for the "emergency" demonstration, a project that falls outside CMS's authority.

II. CMS LACKS AUTHORITY FOR THE PMD DEMONSTRATION

We cannot overstate that CMS lacks the legal authority to embark on the proposed demonstration project. Tellingly, when CMS first announced the demonstration on November 15th, the Agency did so without citing any specific congressional authorization, but rather only referenced the fact that the President had announced several goals to cut down on fraud and improper payments in Medicare. Such policy objectives hardly amount to legal authorization,

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[9] *See* John Graham, Guidance on Agency Survey and Statistical Information Collections, p.6 (Jan. 20, 2006) (noting that emergency clearance "should only be sought if the agency could not have reasonably foreseen the circumstances requiring the collection").

[10] 44 U.S.C. 3507(h)(3). *See also Darrell Andrews Trucking v. Federal Motor Carrier Safety Admin.*, 296 F.3d 1120, 1132-33 (D.C. Cir. 2002)(noting that a material change in the meaning of a regulation or a deviation in the new collection request from OMB's original understanding of a prior collection approval may require a new approval).

[11] CMS, Supporting Statement for Paperwork Reduction Act Submissions, Medicare Fee-for-Service Early Review of Medical Records (CMS-10417), p.7 (Dec. 5, 2011).

and CMS's silence regarding any actual congressional mandate is significant. In fact, Secretary Sebelius announced on November 15th that while CMS had "shown real progress in cutting waste," it "still need[ed] Congress to act on the President's proposal."[12] Though Secretary Sebelius added that "[u]ntil Congress acts," CMS would do everything in its power "to save money on behalf of the American people," her announcement in itself acknowledges the lack of legal standing to proceed with proposals such as the PMD demonstration project. PMD suppliers are ready and willing to help CMS accomplish its goals, but not through a system that blindly scrutinizes all genuine claims without at least attempting to find a rational approach.

In a supplemental "Emergency Justification" to OMB, however, CMS for the first time points to Section 402(a)(1)(J) of the Social Security Act as authority for the demonstration.[13] This provision is part of the Medicare statute's general authority for "[g]rants and contracts to develop and engage in experiments and demonstration projects," captioned "Incentives for economy while maintaining or improving quality in provision of health services."[14] CMS in attempting to justify its proposal, overlooks that its statutory authority is circumscribed. Experiments and demonstrations are by definition narrow in scope. They are used to test a new approach on a small scale, and are not appropriate for a project that would affect forty-three percent of the market, as would occur here.

Even if the PMD demonstration was limited to a smaller geographic area, it still cannot qualify under Section 402 for two important reasons. First, 402(a)(1)(J) authorizes demonstrations for only limited purposes, specifically "to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the [Social Security Act]."[15] The proposed PMD demonstration is not designed to improve methods to investigate and prosecute fraud, but rather to prevent improper payments. Also telling is that CMS would impose a uniform mandatory advance determination requirement with an arbitrary penalty of a twenty-five percent payment reduction, further evidence that the project's focus is payment-driven.

Further, the statutory demonstration authority also limits experiments and demonstrations by requiring comments from specialists. The provision states that "[n]o experiment or demonstration project shall be engaged in or developed ... until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project, and its relationship to other similar experiments and projects already

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[12] The White House, Office of the Press Secretary, "We Can't Wait: Agencies Cut Nearly $18 Billion in Improper Payments, Announces New Steps for Stopping Government Waste" (Nov. 15, 2011).

[13] CMS, Emergency Justification Supporting Request for Emergency Clearance of the Paperwork Reduction Act Package for Medicare Fee-for-Service Early Review of Medical Records (CMS-10417).

[14] 42 U.S.C. § 1395b-1 & 1395b-1(a).

[15] 42 U.S.C. § 1395b-1(a)(1)(J).

completed or in place."[16] We are not aware of any effort by CMS to obtain any advice or recommendations before announcing its PMD demonstration project.[17]

We also note at this juncture that CMS's announcement of the demonstration project runs afoul of the notice and comment requirements of the Administrative Procedures Act ("APA"). Before undertaking significant and new action of this nature, federal agencies must engage stakeholders, which includes receiving suggestions and offering responses regarding how best to implement the proposed policy. CMS has followed the APA in implementing prior demonstration projects,[18] and also engaged in extensive notice and comment with regard to the regulatory revisions of the PMD documentation and payment system itself.[19] The proposed PMD demonstration project merits at least this much interaction with relevant stakeholders—if not far more—yet it is plain that CMS has made no such efforts.

CMS consciously sought no feedback whatsoever and instead elected to issue its proposals as a *fait accompli* just 45 days before they are to take effect. The CMS request is not a true "emergency" and contravenes a key purpose of the PRA, which is "to improve the responsibility and accountability of the Office of Management and Budget and all other federal agencies ... to the public for implementing information collection review process."[20]

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In sum, Hoveround urges OMB to reject CMS's emergency information collection request. We appreciate the opportunity to comment and may be reached for further information at (202) 637-2200.

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[16] 42 U.S.C. § 1395b-1(b).

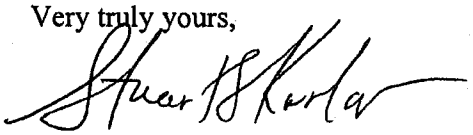
[17] Similarly, CMS cannot rely on the Improper Payments Elimination and Recovery Act ("IPERA"), Pub. L. No. 111-204, 33 U.S.C. § 3321 (note) (2010), to provide a legal foundation for its proposed PMD program. While IPERA instructs all federal agency heads to "identify all programs and activities that may be susceptible to significant improper payments" and "report on what actions the agency is taking to reduce improper payments," the law does not confer complete discretion regarding the means employed or the objectives sought. In addition, IPERA requires the reports to provide evidence of the agency's due diligence, including, among other things, a statement regarding whether the agency has sufficient resources to implement its plan and "program-specific and activity-specific improper payment reduction targets that have been approved by the Director of Office of Management and Budget." To our knowledge, CMS has not complied with these additional requirements.

[18] *See, e.g.*, 75 Fed. Reg. 73483-84 (Nov. 29, 2010); 75 Fed. Reg. 19678, 19704 (Apr. 15, 2010); 70 Fed. Reg. 4130, 4131 (Jan. 28, 2005).

[19] *See, e.g.*, 70 Fed. Reg. 50939 (Aug. 26, 2005); 75 Fed. Reg. 73170, 73390-94 (Nov. 29, 2010).

[20] 44 U.S.C. § 3501(11).

Very truly yours,



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