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VIA Hand Delivery in Washington, DC Office

September 25, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Reference: File Code CMS-1304-P -- Comments Related to Proposed Rule re: Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment (July 28, 2006)

Dear Dr. McClellan and Deficit Reduction Act Implementation Team:

Thank you for the opportunity to provide written comments in response to the Notice of Proposed Rule Making (NPRM or Proposed Rule) related to the planned implementation of the Deficit Reduction Act of 2005 (DRA or Act).

The Proposed Rule relates to the Centers for Medicare & Medicaid Services' (CMS) plans to implement the statutory directives associated with certain home medical equipment and services, home oxygen therapy and related services. The Proposed Rule also includes information about the Part A home health prospective payment system rate update. Since Apria is not a Part A provider, we are not commenting on that section of the Proposed Rule except to say that, just as CMS recognizes that home health nursing involves a number of patient support services outside of direct in-home patient care, it should also realize that patients who rely on home oxygen and medical equipment also require a number of non-equipment services. The cost of these services and overhead associated with managing a quality, responsive home oxygen/HME company cannot be overlooked when CMS attempts to set "fair and reasonable" rates for these Part B services.

IMPLEMENTING THE DEFICIT REDUCTION ACT

Implementation of the DRA is an incredibly complex undertaking due to the unprecedented, untested nature of the Act's requirements. No more than 10% of Medicare beneficiaries have ever taken ownership of their traditional home medical equipment and few, if any, oxygen-dependent beneficiaries, most of whom are frail and elderly, have ever owned their own equipment and been responsible for routine maintenance and service in the manner that Congress expects.

The CMS team responsible for developing the implementation guidelines is faced with navigating through uncharted territory. Unlike the planned competitive bidding program for DMEPOS which attempts to mirror some of the competitive bidding techniques employed by private managed care organizations, no other payor in America requires patients to take ownership of their oxygen equipment and caps the payment for oxygen therapy at 36 months or any other interval. We will provide comments to the best of our ability, but unfortunately we do not have experience in working within a capped reimbursement/ownership-required environment for oxygen patients. Apria – along with every other home oxygen provider in America – is faced with a large number of unknown factors when considering how services ultimately will be provided to patients under the final rules.

However, Apria is America's largest provider of DME, respiratory care services, home enteral nutrition and home infusion therapies, and therefore we serve a large number of Medicare beneficiaries. We interact with and understand the needs of tens of thousands of referral sources that work in hospitals, clinics and physician offices. Therefore, we will share certain observations with you as a result of that experience in the hope that you will reconsider some of the more restrictive aspects of the proposed rules. Our goal, which CMS likely shares, is to preserve patient and referral access to homecare services and products under the Medicare Part B oxygen and DME benefits.

Because the home medical equipment and oxygen therapies addressed by this Proposed Rule will also be subject to DMEPOS competitive bidding, Apria is also including comments about how the two separate initiatives, the Medicare Modernization Act's (MMA) competitive bidding provision and the DRA's capped rental/transfer of ownership provision) overlap. In many ways, these proposed programs conflict with each other.

BACKGROUND ON APRIA HEALTHCARE

With over 500 wholly-owned respiratory/medical equipment branch locations nationwide, Apria serves patients in all 50 states, including those covered by Medicare, Medicaid and managed care plans. We provide direct care to hundreds of thousands of Medicare beneficiaries each year, and contract with over 2,500 managed care plans as well. In terms of payor mix, managed care revenue represents about 65% of our $1.5 billion of annual revenues, while 35% is comprised of Medicare/Medicaid revenues.

We own and operate 32 home infusion pharmacies that provide extensive clinical and patient support services to patients who require intravenous therapies to treat a wide range of chronic and acute conditions. Apria also owns and operates three centralized clinical respiratory pharmacies that serve patients who require inhalation drug therapies and support services necessary to treat Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States.

The Company also provides custom rehabilitation equipment and services and diabetic supplies to patients covered by Medicare, Medicaid and certain managed care insurers.

All facilities are licensed by all of the states in which we operate, and we fill orders and prescriptions written by physicians who are licensed in those states. We employ over 10,000 people nationwide.

APRIA HONORED WITH "ETHICS IN AMERICA AWARD" IN SEPTEMBER 2006

As part of our overall commitment to compliance, Apria operates a robust corporate compliance program that includes an employee hotline, disclosure methods, checks against debarment databases, mandatory employee training on fraud and abuse topics and other features. Our Board of Directors has been recognized nationally for its corporate governance measures and, on September 19 of this year, Apria received the Ethics in America Award in the category of "National Public Company," sponsored by the Passkeys Foundation, an independent, non-profit organization that is dedicated to "building a nation of character." The Passkeys Foundation Board voted unanimously to award Apria with the Ethics in America Award due to its demonstrated commitment to operating the Company in a compliant and ethical manner.

ORGANIZATION OF OUR COMMENTS

We have organized our comments on the Proposed Rule as follows:

1. An Executive Summary to highlight our most significant comments and concerns about the Proposed Rule, and

2. Detailed Comments on the areas of concern, including concrete suggestions for improvement and recommendations for CMS to incorporate into its Final Rule and implementation plan for the DRA.

CONTACT INFORMATION FOR QUESTIONS ABOUT COMMENTS

Due to the extensive nature of these comments, questions may arise about them as the CMS team undertakes their review. Please feel free to contact the following Apria Healthcare employees who are leading our efforts on the DRA and its implementation in our company:

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SUMMARY

When one considers the primary cost drivers associated with the Medicare system, home healthcare is not the problem; rather, it is part of the solution. Medicare spending on home healthcare in total has remained relatively flat for several years and in recent publications, CMS has attributed the increased Part B costs to hospital outpatient and physician services. Home healthcare offers a number of patient care and cost-savings advantages to patients as well as the Medicare program.

The numerous reimbursement changes impacting DME and oxygen as early as 2007 must be carefully implemented in an effort to avoid a significant disruption not only in the homecare industry, but also among existing and future patients and their referral sources. In the spirit of cooperation, we have provided CMS with detailed comments in an effort to help shape the final rule so that its requirements are grounded in the realities of caring for Medicare beneficiaries at home.

We appreciate the opportunity to provide you with these comments and welcome any questions you may have in the coming months as you review what will likely be a significant number of comments from individual stakeholders.

I also want to reiterate Apria's invitation to welcome you and any member of the CMS team to Apria's Philadelphia branch to gain a more comprehensive understanding of home oxygen therapy and medical devices and the ramifications of the proposed policies.

Sincerely yours,

Lawrence M. Higby / T.C.S.

Lawrence M. Higby
Chief Executive Officer

CC: Herb Kuhn (Executive Summary Only)

APRIA HEALTHCARE

Comments Related to Proposed Rule re: Home Healthc Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment

[CMS-1304-P]

EXECUTIVE SUMMARY

Introduction

As noted above, Apria is the nation's largest provider of home respiratory, infusion and medical equipment services as well as the largest provider of these services to managed care organizations. Apria is therefore in a unique position to CMS with information and input on how other major health insurers approach the homecare market. In prior comments, we have shared information about how the private sector addresses home infusion therapy, inhalation therapy, bidding among competitive homecare providers, contracting, provider selection criteria, performance and quality standards, accreditation, patient satisfaction, and the use of electronic interfaces.

Unlike DMEPOS competitive bidding, which the government piloted in two demonstration markets before proceeding with a nationwide expansion plan, the Deficit Reduction Act of 2005 (DRA) introduces all-new concepts regarding certain home medical equipment and oxygen therapy, services and equipment that have no precedent in the government or private sector. Managed care organizations do not and have never transferred ownership of oxygen equipment to their members, and they do not limit or "cap" the number of months that they reimburse for patients who require medical oxygen therapy. Even the Veterans Administration (VA) healthcare system that is so often used as a comparative model, despite the significant differences from Medicare, does not mandate transfer of the title of medical equipment to the patient. Nor does the VA cap the reimbursement for oxygen equipment for any length of time as long as a medical need for it exists.[1,2]

[1] Apria Healthcare and homecare provider contracting experience with over 2,500 managed care organizations and the Veterans Administration.

[2] Office of Inspector General, Home Oxygen Equipment: Cost and Servicing, OEI-09-04-00420 (Sept. 2006), at 5 ("OIG Oxygen Report:").

Unknown Cost Impact of the DRA on Medicare Part A Expenses

Readily available data from CMS indicates that an entire year of Medicare home oxygen therapy costs the government only slightly more than a single day that a COPD patient spends in a typical hospital. The Department of Health and Human Services' experts on patient quality, access and evidence-based medicine, the Agency for Healthcare Quality and Research (AHRQ), released a comprehensive study in 2004 of the effect of Long-Term Oxygen Therapy (LTOT) on patients' health and related health care utilization. Ringbaek et al. (2002) reported that the average number of hospital admissions per patient per year decreased from 2.1 to 1.6 and the average number of days hospitalized decreased from 23.7 to 13.4 after LTOT.[3] Medicare's current estimate for one day of hospitalization is $1,600, which of course includes reimbursement for all of the direct and indirect patient care services, supplies, any oxygen and/or inhalation drug therapy needed, equipment and overhead in order to provide such care in a hospital setting.[4] Therefore, at $1,920 for one year of home oxygen therapy, Medicare obviously saves a significant amount of money by relying on homecare instead of institutionalization for these patients, and that is before the DRA or any other cut takes place.

With the DRA, CMS and homecare providers are entering uncharted waters together. In our view, the proposal reflects a troubling approach to implementation, since literally hundreds of thousands of Medicare beneficiaries will be impacted by these policy changes beginning as soon as February 2007. This is when the first patients take ownership of hospital beds, wheelchairs, patient lifts, CPAPs, nebulizers and other medical equipment. We understand that the statute, as written, does not appear to furnish CMS with much flexibility regarding implementation of the period for title transfer. Yet, many questions remain unanswered as to how they will be expected to obtain certain services that have heretofore been included in the monthly bundled payment rate or covered by the former semi-annual service and maintenance fee that Medicare historically has paid to homecare providers for HME capped rental.

Therefore, prior to implementing the current proposal, we recommend CMS conduct a study in a clearly-defined marketplace to ascertain the level of rehospitalization, emergency room visits, physician office visits or other Part A/B expenses incurred as a result of patients being unable to access a qualified provider to furnish appropriate clinical expertise or respond to general equipment questions after the patients assume ownership of the medical equipment.

CMS: Faced with Implementing a Flawed Public Policy

In fact, we are sympathetic to the CMS team faced with having to implement such a flawed public healthcare policy, since there are no real precedents to draw upon. It is evident that the CMS team made a good faith effort to draft proposed policies to implement certain aspects of the Act in order to presumably safeguard beneficiaries from potentially abusive practices, and again we understand your concerns.

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[3] Long-Term Oxygen Therapy for Severe COPD, June 11, 2004, Lau, et al. Tufts-New England Medical Center Evidence based Practice Center (EPC), under contract to the Agency for Healthcare Research and Quality Agency for Healthcare Research & Quality (AHRQ) Rockville, MD, op. cit., footnote #1, page 23.

[4] CMS Office of the Actuary, Medicare Cost Reports for Hospitals – updated with cost reports submitted as of March 31, 2006.

However, certain proposed procedures that CMS would require providers to follow are simply not feasible or practical in terms of the day-to-day operating realities of homecare operations and the services that patients have come to expect from home oxygen and medical equipment providers. To our knowledge, the CMS employees assigned to develop this Proposed Rule have not visited any provider's site to gain a better understanding of the operating realities. Finally, we believe that CMS has proposed certain policies that are not mandated by either the DRA or any other statute and are therefore overreaching in nature.

Key Issues with the Proposed Rule

Again, we want to emphasize that we appreciate the challenge that CMS faces in regard to the DRA. Aside from sharing our concerns with you, wherever possible, we will provide you with a recommended alternative to the proposal found in the Proposed Rule.

Our primary concerns with the Rule fall into nine (9) major categories:

1. **Proposed Rule is Not Budget Neutral as Mandated by Statute** – The proposed payment structure for various oxygen modalities is not budget-neutral as statutorily mandated, and other policy changes contained in the Proposed Rule are not based on any other existing statute. The Proposed Rule's rates represent a 10.3% payment cut beginning January 1, 2007. The Proposed Rule does not comply with the Social Security Act (SSA), Deficit Reduction Act of 2005 (DRA) or Benefits, Improvements and Protection Act of 2000 (BIPA). The statute is quite explicit that there must be neutrality in <u>every</u> budget year. Applying the CMS information disclosed in the Proposed Rule, as demonstrated later in these comments, it appears that CMS's budget changes are not neutral for <u>each</u> year. In the unlikely event that the proposal is budget-neutral, CMS has not explained how that is so in a manner that permits appropriate external evaluation and opportunity for comment.

We outline the analysis that demonstrates the 10.3% reduction in the detailed comment section that follows this Executive Summary.

2. **Reimbursement Reallocation is Needed for a Few Oxygen Modalities** – As stated above, any payment rate changes for oxygen that CMS develops must be budget neutral as mandated by law. We have estimated a 10.3% payment rate reduction from current Medicare oxygen expenditures of approximately $2.6 billion. This translates to approximately $260 million (the "left over amount") that CMS must reallocate to certain oxygen modalities for which the proposed rates are inadequate to cover providers' costs to service patients who require those modalities. Our recommendation is that CMS reallocate the left over $260 million to two categories, contingent on the other categories remaining as proposed (*i.e.*, the proposed rate for concentrators of $177 would remain the same in this reallocation).

We recommend that the $260 million should be reallocated to the payment categories most in need of an upward adjustment in order to cover providers' costs to provide them. They are: 1) delivery of portable contents both before and after the 36-month maximum rental period is reached, and 2) stationary <u>and</u> portable liquid oxygen starting from day one in 2007 or whatever day the new rates take effect. As an example of the cost differential between modalities, liquid oxygen costs providers 20-30% more to acquire assets, 40-50% more for delivery and 4-10% more for repairs.

Delivery frequency for portable cylinders must be incorporated into CMS' allowable for portability. Patients who rely on gaseous cylinders typically require 1.5 deliveries per month on average, while patients who rely on liquid require 2.0 deliveries per month. The Morrison Study provides delivery, equipment exchange and overhead cost information. It also shows that the modality-blended average

number of deliveries per patient is 1.6 per month.[5] (We do not agree with the OIG Report's assertion that cylinder delivery frequencies are quarterly.[6] Without the benefit of reviewing the OIG's data, we may only assume that a calculation error occurred or that the patient sample was slanted toward those patients who use nocturnal oxygen only and therefore require less frequent deliveries of oxygen cylinders that are used primarily as emergency back-up systems.)

Accordingly, we recommend that CMS adjust the proposed rates as follows:

- **Portable Contents (Gaseous)** should be paid in the range of $75 to $80 per month, starting on day one of the new payment rate schedule and continuing at that rate beyond the 36th month;
- **Liquid stationary** may remain at CMS' proposed rate of $177 per month, as long as the **liquid portable** rate is adjusted to be in the range of $90 to $95 per month in both the pre-36-month and post-36-month scenarios;

By reallocating in this manner, CMS will achieve budget neutrality.

3. **Non-Equipment Services Must be Recognized** – CMS, Congress and the OIG demonstrate a lack of understanding for the non-equipment services and costs that providers supply and incur when caring for Medicare oxygen beneficiaries. (Actually, these are the same services and costs incurred when caring for any oxygen-dependent person, regardless of their payor source. The difference is that certain services associated with Medicare cost providers more than for managed care, such as the patient intake/admission process, the Certificate of Medical Necessity (CMN) document preparation, distribution and retrieval process from physicians, and Medicare billing costs.) Morrison Informatics' comprehensive study of the service elements and their costs concluded that oxygen equipment and related accessories represent 28% of providers' total costs to care for Medicare oxygen beneficiaries, while 72% of the costs are represented by other patient support and administrative services.[7] This includes certain services that will continue to be available to patients with a length-of-stay of less than 36 months on oxygen that may not be available to patients after the 36th month. This may impact the quality of patient care and access to items and services critical to the safety of oxygen patients. This also may establish a potentially discriminatory situation for CMS.

4. **A Transition Period and Grandfathering Process is Needed to Operationalize Changes Mandated by the Proposed Rule** – There are significant operating challenges associated with the proposed policy changes and they will impact CMS, providers, patients and referral agents alike. More time is needed for providers to re-program information systems and establish certain business practices that were never required before the DRA. Significant examples of this include:

[5] *Id.*, at 6.
[6] OIG Oxygen Report, at 12.
[7] *Id.*, at 2,7.

- Developing procedures and programming information systems to enable tracking cumulative repairs and related costs at the serial number level,

- Managing the patients' ownership of portable oxygen cylinders that have historically been operationally fungible and modifying policies and procedures to conform to the new requirement while still maintaining FDA medical gas compliance,

- Developing processes and systems for providing official notification of transfer of ownership for a significant increase of the number of patients to whom the ownership of medical devices is transferring. Historically, in our experience, less than 10% of capped rental DME patients chose the purchase option,

- Developing communication materials that would address the changes in ownership requirements and responsibilities for patients between the time the Final Rule is published and it takes effect, and

- Documenting a change in medical condition that would justify a patient's equipment switch and therefore avoid Medicare claim denials or an increase in bad debt write-offs due to non-coverage by CMS.

CMS should also allow for a grandfathering process that would allow those patients who were initiated on oxygen service on January 1, 2006 or thereafter to be billed at the prior rates and managed per the former policies, such as having the ability to switch equipment if the patient or physician chooses. A grandfathering process would also allow providers and patients time to effect a smooth transition, thus avoiding a large increase in depreciation or asset write-off expense that could be associated with the change in payment approach for various modalities. CMS has adopted grandfathering processes in the past, as in the example of its interpretation of the DRA's provisions for capped rental home medical equipment. Patients initiated on to service prior to January 1, 2006, are reimbursed under the former rates and rules, while only new patients must be managed under the DRA's provisions. This will allow an appropriate transition period for all stakeholders involved.

5. **Stakeholder Impact Has Not Been Evaluated** – Because the ownership provision and capped oxygen rental aspect of the DRA have never been studied before, patients and their clinical care providers will be impacted in ways not yet contemplated by the Agency. For example, patients frequently contact their oxygen providers to request another modality that they may have seen at a Better Breathers meeting. If the patient could tolerate the alternative modality (such as switching from an oxygen concentrator plus gaseous portable oxygen to a liquid base system and liquid portable), the provider usually simply exchanges the equipment for the patient after obtaining a new prescription from the patient's physician. If the provider could not or would not accommodate the request, historically, the patient always retained the right to change providers.

Under the Proposed Rule, the provider will not be able to switch out the equipment in response to a patient's request, even with a physician prescription. A change in medical condition must apply, and neither the definition of nor the process for documenting a change in medical condition has been published by CMS. Moreover, a patient's right to change providers to obtain another modality will also be restricted. Since there may only be a few months left on the 36-month maximum rental cycle, the new provider might be unwilling to provide the patient with expensive equipment when the costs will not be covered by Medicare. Physicians may also elect to accommodate a patient's desire to switch modalities, but unless a change in medical condition applies under the new Rule, their request cannot be

accommodated. The homecare provider will be placed in the middle of this situation and will have to explain the new rules to both patients and physicians.

6. **Certain DRA Provisions and Planned Competitive Bidding Overlap and Conflict With Each Other** – The Proposed Rule does not recognize the potential conflict and overlap between the CMS plans to implement the DRA and how those proposed policies and plans overlap with the DMEPOS competitive bidding planned for 2007. In fact, some of the provisions in the Proposed Rule actually conflict with competitive bidding, so we are looking to CMS to clarify the conflicts in the final rules concerning both competitive bidding and the DRA. Additionally, the revised 10% competitive bidding savings level for oxygen that was included in the Proposed Rule concerning competitive bidding may be greatly reduced if any other reductions are made to oxygen payment levels prior to the implementation date for competitive bidding.[8]

7. **The Proposed Rule Presents Legal Concerns** – Apart from the lack of budget neutrality, here are seven (7) main elements of the Proposed Rule that cause significant legal concerns. These include the areas of equipment repair, maintenance and replacement after oxygen equipment ownership transfers to patients; the need for standardized allowables for repair parts and labor; requirements related to replacing patient-owned equipment; the "sixty percent rule;" average useful life definition; Medicare Assignment notification requirements and potential liability for providers after transfer of ownership. Many of these legal concerns arise out of a lack of statutory authority for CMS to implement many of these requirements under the Proposed Rule.

8. **The Proposed Rule Does Not Conform to the Data Quality Act (DQA)** – There are numerous examples where CMS has not provided any data, studies, scientific references, clinical literature references, market information, manufacturers' suggested retail pricing, provider survey data or any other analyses that explain how it developed its assumptions, suggesting these are unsupportable or inaccurate. Specific examples include the frequent references to CMS' "belief" that certain payment levels are "too high" or "too low," or that "some people believe" that providers select one oxygen modality over another for financial reasons. Another example of a data integrity issue is CMS' published data that suggests 36% of all oxygen beneficiaries exceed the 36th month of rental, while the Office of Inspector General (OIG) recently published a 22% figure.[9] None of the putative data in the Proposed Rule is supported by any references to data extracts, focus groups or formal studies. Even the baseline budget year is not revealed, nor are estimated growth rates, shifts in oxygen utilization or other critical factors. We have reviewed the explicit requirements of the Health and Human Services (HHS) DQA Guidelines concerning objectivity, transparency, quality, non-bias and other attributes, and believe it is clear that the Proposed Rule has not met the threshold requirements of the DQA.

9. **September 2006 OIG Study on Medicare Oxygen Payment Contained Invalid Data and Comparisons** – The September 14, 2006 release of the OIG study on oxygen entitled "Medicare Home Oxygen Equipment: Cost and Servicing," provides us with the opportunity to include comments that describe the flaws in the OIG's data, methodology, recommendations and comparisons. Apria Healthcare cooperated fully with the OIG and hosted the Project Leader at its Sacramento, California branch so that she could witness the full range of services that are associated with serving oxygen patients, regardless of their payor source. She also observed the tremendous administrative burden associated with the Medicare Oxygen Certificate of Medical Necessity (CMN) preparation and retrieval process, repair center and associated overhead expenses, clinical respiratory services and expenses and two- to four-hour delivery time from the point of referral. None of these costs were acknowledged or given even a cursory reference in the OIG report. Thus, it resulted in a very slanted, inflammatory and inaccurate representation of

[8] 71 Fed. Reg.
[9] Id., at 8.

Medicare "equipment and servicing." The OIG Oxygen Report did not comply with the OIG's internal guidelines for the Data Quality Act (DQA) either. We will provide more information on these and other concerns about the OIG Report in the "Detailed Comments" section that follows.

Summary

We appreciate the time and effort that CMS staff invested in developing the Proposed Rule. In principle, we agree with the general direction CMS has proposed in terms of establishing different payment levels for different oxygen modalities. However, the new payment levels are not budget neutral as mandated by statute, and actually represent a payment cut of approximately 10.3% starting in January 2007. Therefore, we recommend that CMS reallocate the approximately $260 million reduction to increasing the payment rates for portable gaseous oxygen, liquid oxygen (stationary and portable) and self-generating oxygen systems. This will more adequately reimburse providers for the total operating costs associated with providing these modalities and services to patients who need them.

Despite our general agreement with the modality-specific payment levels, we believe that the provisions of the DRA regarding the transfer of ownership of FDA-approved medical devices and the 36-month cap are flawed policies that have not been studied or evaluated by the government in any meaningful way. Additionally, certain policies that CMS has proposed in the Proposed Rule are fraught with challenges in terms of implementation, communicating the changes to patients and referring physicians and achieving CMS' stated goals for the Proposed Rule. Additionally, certain aspects of the Proposed Rule do not comply with the DQA and accordingly cause us to be concerned that the implementation may be interrupted by injunctions or other litigation. We will welcome CMS' clarification of several unclear areas when it publishes its final rule in the near future.

Finally, due to the likelihood that patient care and the industry will be disrupted by any precipitous move on the agency's part, we recommend that the final rule allow for a transition period before implementing the final payment rates and policies. This is particularly important since the changes described in the Proposed Rule represent an all-new payment system, and since the final rule may not be published until late November. Extra time is needed for providers to prepare to adjust to the changes.

Additional detail about these concerns follows this Executive Summary.

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DETAILED COMMENTS ON PROPOSED RULE

[CMS-1304-P]

1. Proposed Oxygen Payment Rates Are Not Budget-Neutral as Mandated by Statute

Although the Social Security Act (SSA or Act) authorizes CMS to establish new classes of oxygen and oxygen equipment, this must be done in a manner that is consistent with all applicable provisions of the Act. As a matter of plain language, CMS' authority to create budget-neutral classes of an oxygen modality or equipment item in section 1834(a)(9)(D) does not nullify the payment rules that govern other items in sections 1834(a)(5), (9)(C), and (21). The latter provisions provide a specific formula for calculating monthly payment rates for the different items of oxygen and oxygen equipment, which after 1999 are based on 70% of the national limited monthly payment rate for that item, plus an adjustment to bring Medicare spending on these items into line with other federal spending.

In the Proposed Rule, for two oxygen items – stationary equipment and stationary oxygen contents – CMS did not create special classes within those items. Thus, the Act mandates that CMS continue to calculate the payment amounts for those two items pursuant to the rate set by the Act at sections (1834(a)(15), (a)(9)(C), and (a)(21). CMS failed to do this. Instead, it simply reduced the required payments for these items to make up for the increased budget costs of the new classes that it created in the Proposed Rule. We assert that the statute does not permit this; for items where CMS does not exercise its authority to create classes, payment must be made at the rate set by statute.

Secondly, CMS has violated the requirement that any changed payment rates for item classes will "not result in *expenditures for any year* to be more or less than the expenditures which would have been made if such actions had not been taken." 42 U.S.C. § 1395m(9)(D)(ii) (emphasis added). While not disclosing its budget data, CMS indicates only that the proposed increases and decreases in expenditures should be roughly equal over the next two or three years. **The statute is quite explicit that there must be neutrality in <u>every</u> budget year. Applying the CMS information disclosed in the Proposed Rule, as demonstrated later in these comments, it appears that CMS's budget changes are not neutral for <u>each</u> year. In the unlikely event that the proposal is budget-neutral, CMS has not explained how that is so in a manner that permits appropriate external evaluation and opportunity for comment.**

Informal rulemaking of the kind that CMS proposes requires that the agency's factual conclusions must be reasonable and not arbitrary and capricious, and the public's right to participate in a notice-and-comment proceeding means that "at least the most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation." *Association of Data Processing Serv. Orgs. v. Board of Governors*, 745 F.2d 677, 685 (D.C. Cir. 1984) (Scalia, J.); *Air Transp. Ass'n of Am. v. F.A.A.*, 169 F.3d 1, 7 (D.C. Cir. 1999) (same); *Athens Cmty. Hosp. Inc. v. Shalala*, 21 F.3d 1176, 1179 (1994) ("A decision resting solely on a ground that does not justify the result reached is arbitrary and capricious.")

Here, the agency has stated (without the disclosure of any analysis) that Medicare "believes" that the monthly payment for stationary equipment and contents of $199 is "too high" and that the $21 payment for furnishing oxygen contents for beneficiary-owned portable equipment is "too low." Further, CMS states that it "believes" that the payment of $156 for oxygen contents for stationary-and-portable users creates "an incentive for suppliers to furnish stationary oxygen systems that require the ongoing delivery of oxygen contents," rather than concentrators and transfilling equipment that self-generate oxygen in the beneficiary's home. 71 Fed. Reg. at 44096.

We were surprised and disappointed by CMS' lack of disclosure of what data led to these "perceptions" since they were presented as factual assumptions without any documentation to support the assertions. The agency is required to "'retain a duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a nonarbitrary, non-capricious rule,' and therefore must justify its basic 'assumption[s] even if no one objects ... during the comment period.'" *Northeast Md. Waste Disposal Auth. V. E.P.A., 358 F.3d 936, 948 (D.C. Cir. 2004).*

Using Medicare's own data regarding the current oxygen modality mix that was included in the Proposed Rule, the proposal represents a 10.3% reimbursement cut beginning in January 2007. The chart on the following page illustrates this point using a sample of 10,000 Medicare beneficiaries and applying the exact oxygen modality mix that CMS describes in the Proposed Rule, which is:

- 69% of patients using both stationary concentrator and portable systems of gaseous or liquid;
- 5% using stationary gas or liquid and a portable of the same;
- 24% using stationary concentrators only, and
- 2% using only a stationary plus liquid or gas system.[10]

[10] 71 Fed. Reg.

PROPOSED MEDICARE REIMBURSEMENT REDUCTIONS "BUDGET NEUTRALITY" CALCULATION

	1 - 12 mos	13 - 24 mos	25 - 36 mos	TOTAL
PATIENT MONTHS				
Monthly Patients on Service	10,000	10,000	10,000	
Patient Months - Equipment Rental & Contents	120,000	120,000	120,000	
Patient Months - Contents for Beneficiary-Owned Equipment	0	0	0	
	120,000	120,000	120,000	
PROPOSED WEIGHTED REIMBURSEMENT RATES, EFFECTIVE 1/01/2007				
Equipment Rental & Contents	$201	$201	$201	$201
Contents for Beneficiary-Owned Equipment	-	-	-	-
Annual Reimbursement per Patient	$2,408	$2,408	$2,408	$2,408
GROSS REVENUE				
Equipment Rental & Contents	$24,081,600	$24,081,600	$24,081,600	$72,244,800
Contents for Beneficiary-Owned Equipment	-	-	-	-
	$24,081,600	$24,081,600	$24,081,600	$72,244,800
WEIGHTED REIMBURSEMENT RATES				
Equipment Rental & Contents	$(23)	$(23)	$(23)	$(23)
Contents for Beneficiary-Owned Equipment	-	-	-	-
Net Effect of Proposed Reimbursement Changes per Patient	$(276)	$(276)	$(276)	$(828)
GROSS REVENUE				
Equipment Rental & Contents	$(2,760,000)	$(2,760,000)	$(2,760,000)	$(8,280,000)
Contents for Beneficiary-Owned Equipment	-	-	-	-
	$(2,760,000)	$(2,760,000)	$(2,760,000)	$(8,280,000)
	-10.3%	-10.3%	-10.3%	-10.3%

CMS' Proposed Payment Levels for 2007: Payment Rate Cut of 10.3% Starting in January 2007. This is before competitive bidding or the DRA.

As the reader can plainly see, the proposed rates are not budget neutral in any of the initial years in which the new rates would take effect. Once years four and five are evaluated, which represent a 4.3% cut in each of those years, it translates to a cumulative cut of 8.3% over five years. Moreover, despite several sections in which certain calculations were provided by CMS, they in no way meet the threshold for quality, objective, transparent, scientific data as directed by the Data Quality Act (DQA) and the implementing CMS guidelines.[11] Should CMS move forward with its proposal as presented, we could only conclude that the decision would be arbitrary and capricious because it would appear to be supported by invalid data or based upon inaccurate assumptions.

To illustrate this point, in the Proposed Rule, CMS projected that its new payment structure would result in an $11 million annual increase in payments for oxygen contents delivered to beneficiaries who own portable equipment, but it did not disclose the calculation or the underlying data. CMS simply stated that "[t]his figure is based on current data on utilization of portable oxygen by Medicare beneficiaries."[12] It is impossible for any commenter to evaluate the accuracy of this statement and the assertion of a payment increase. CMS similarly failed to support its claim that the increased add-on payment for oxygen-generating equipment would result in an annual increase of $5 million in payments. Since CMS anticipates that suppliers might choose different modalities in response to the changed payment rates, the agency is required by the DQA to model the dynamic effects of the changed payment structures on utilization to ensure budget neutrality at the new rates, and to offer both the data and the model (including assumptions and methods) for public comment.

In addition, CMS never explained how it calculated the offsetting annual $16 million decrease by reducing the stationary equipment monthly payment from $199 to $177 and creating a stationary contents payment. We presume CMS must have usage statistics on which these statements are based. To survive review under the arbitrary-and-capricious standard, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983).

This deficiency is particularly glaring because CMS has assumed that changing the payment structures would have a dynamic effect on provider behavior. CMS states that the current payment structure created incentives that caused suppliers to supply certain kinds of equipment, 71 Fed. Reg. at 44095, and has specifically suggested that the new equipment and contents classes and rates could "potentially [cause] a shift in utilization between the various oxygen equipment modalities." *Id.* at 44104. Yet, again, CMS does not provide any budget analyses supporting any such utilization shifts or their impact. Simply speculating that a potential shift may occur does not meet the statutory requirement of ensuring budget neutrality.

Even if CMS had unlimited discretion to set payment rates at any level it desired so long as it maintains budget neutrality, it has not provided a logical or clear explanation that the new class payment rates would "not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken." 42 U.S.C. § 1395m(9)(D)(ii). It has not done so because it has disclosed none of the modality-specific data on usage and spending and has not explained how such data was used in its budget projections.

Our recommendation is to reallocate the approximately $260 million to portability and liquid (both stationary and portable liquid) in order to restore the budget neutrality mandated by law.

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[11] Pub. L. No. 106-554, § 515 Appendix C, 114 Stat. 2763A-153 (2000) (uncodified); Department of Health and Human Services, *Guidelines for Ensuring the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, available at <http://aspe.hhs.gov/infoquality/Guidelines/index.shtml> (last visited Sept. 12, 2006); Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8,452 (2002).

[12] 71 Fed. Reg. at 44097

2. Reimbursement Adjustments Are Needed for a Few Modalities

We understand and agree with the goals of CMS to create a payment system that addresses individual oxygen modalities differently and also increases patient access to new technologies as they evolve.

In general, the proposed payment structure from CMS is feasible, with the critical flaw that it is not budget neutral and results in a net payment reduction of over 10% as illustrated earlier. If it were budget neutral as mandated by statute and the individual payment levels for all modalities were acceptable, there would be little to debate. That is not the case. Therefore, we recommend CMS consider certain adjustments to the reimbursement rates so providers will be able to cover the costs of providing them. Specifically:

- The allowable for the post-36-month gaseous portable systems used in conjunction with a stationary oxygen concentrator (the in-home portable cylinder provision and delivery) **must** be increased. The proposed level is still too low at $55 per month. The Morrison Informatics study provides CMS with current cost data to determine the appropriate level of reimbursement[13]. The proposed rate needs to be increased to take into account the fully-loaded cost of a delivering portable cylinders to patients, including warehouse, FDA/DOT/hazardous materials regulatory compliance, vehicles, fuel, labor, billing and a fair allocation of overhead. Otherwise it is our belief that deliveries will be reduced to once a month, and patient dissatisfaction will increase when they have to have 16-30 cylinders delivered at one time. The current average delivery frequency per patient for gaseous cylinders is about 1-1/2 times per month; for liquid the average is two times per month, although high liter flow patients require four or more.[14] **Morrison study delivery cost information represent delivery only, not the inextricable operating costs described immediately above. In addition, the recommendation provided for the reallocation to portability is contingent on the other modalities remaining as they were recommended in the Proposed Rule (*i.e.*, oxygen concentrators at $177 per month before capping).**
- Reimbursement for liquid stationary and liquid portable oxygen must be increased or there will be no liquid available through providers. Even for Apria, which is the largest liquid oxygen provider in the United States and has the benefit of economies of scale, furnishing liquid is much more expensive that providing other modalities. The acquisition costs for liquid oxygen systems (assets) are about 25 – 30% higher than for gaseous systems, deliveries cost 50 – 60% more, and repair costs are higher too. While CMS indirectly may be trying to phase out this modality, it is very popular with many physicians and highly ambulatory patients, especially in high altitude areas such as the Colorado Rockies geographic area, where concentrators are less efficient due to the thin atmosphere. Any shift away from liquid will need a transition period and the grandfathering of existing patients for the sake of their care. Our experience is that patients who are on liquid have a difficult time switching to gaseous modalities of any kind, including the home transfilling system.

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[13] *Id.*, at page 6.

[14] We strongly disagree with the OIG's assertions in its report, "Medicare Home Oxygen Equipment: Cost and Servicing," OEI-09-04-00420 (Sept. 2006), at ii and 12-13, concerning the frequency of delivery of cylinders, which we presume were used in preparing the Proposed Rule. Industry experience, which the Morrison Informatics study includes, is that the average delivery frequency for cylinders is definitely not quarterly but rather 1.6 times per month, on average. Without seeing the OIG and CMS source data, however, we can only conclude that there was a calculation error or the patient survey sample somehow was skewed toward nocturnal oxygen-only patients. These patients have a much lower delivery frequency, and represent a very small percentage of the total Medicare oxygen population.

Accordingly, we recommend that CMS reallocate the $260 million to bring the budget into a neutral state by adjusting the proposed rates as follows:

- **Portable Contents (Gaseous)** should be paid in the range of $75 to $80 per month, starting on day one of the new payment rate schedule and continuing at that rate beyond the 36th month;
- **Liquid stationary** may remain at CMS' proposed rate of $177 per month, as long as the **liquid portable** rate is adjusted to be in the range of $90 to $95 per month in both the pre-36-month and post-36-month scenarios;

By reallocating in this manner, CMS will achieve budget neutrality.

Grandfather Existing Oxygen Patients Under Former Rates & Policies

We recommend that CMS grandfather existing patients and use the new modality method going forward only for newly-initiated patients in order to prevent massive capital expenditures, the needless abandonment of functional existing equipment and the resulting business disruption. A rapid transition to the new rates without a grandfathering provision would cause large increase in depreciation expense or asset write-offs for providers who could find themselves saddled with a significant amount of excess inventory. Again, all stakeholders, including providers, patients and physicians, need some time to adapt to a new model, procure new inventory, negotiate and sign contracts and modify computer systems and processes.

CMS has several precedents for recommending such a grandfathering procedure. The most recent example is how the HME capped rental patients are being treated under the DRA. For patients whose first date of service was prior to January 1, 2006, the former rates and rules apply. It is only those patients whose first date of service is January 1, 2007 or later that are subject to the new payment levels and rules associated with the DRA.[15]

[15] CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 918, Change Request 5010, "General Provider Education for Changes in the Payment for Oxygen Equipment and Capped Rentals for Durable Medical Equipment (DME) Based on the Deficit Reduction Act of 2005," April 28, 2006.

physician.

The Morrison Informatics study demonstrated that non-equipment costs comprise 72% of providers' total costs.[17] The

4. A Transition Period is Needed to Operationalize Changes Mandated by Rule

Home oxygen and DME providers need access to the Medicare Common Working File in order to ascertain whether patients have had the same or similar equipment before, and the status of their rental period.

Although the home oxygen and DME industry has requested access to the Medicare Common Working File (CWF) in the past, access is more critical than ever before in light of the DRA's provisions. In real time, providers need to understand not only whether a Medicare beneficiary has Part B benefits (this data is retrievable), but also whether the beneficiary has received the "same or similar" equipment from another provider in the past (typically within the previous five years for capped rental HME products). In addition, given the change in the cap period of time for HME (from 15 to 13 months with January 1, 2006 as the start date), and brand-new cap period for oxygen patients (36 months), providers must be able to access historical usage data so that they may understand whether they will be paid for the equipment and services they are being asked to provide within two to four hours of the typical referral.

Our understanding is that home health agencies and skilled nursing facilities have access to the CWF for reasons that similarly justify the access needed by DME/oxygen providers. We are unaware of any specific statute or regulation that would prohibit DME suppliers from accessing the portion of the CWF relevant to beneficiary equipment usage history or obtaining similar information from DME MACs.

If, for example, the patient already owns a nebulizer, CPAP or hospital bed after a 13-month rental period, any homecare provider that supplies a second one because they are unaware or cannot confirm that the patient already has one from another provider will be denied payment by Medicare. However, they will not know this until well after the products and services have been provided and become all but irretrievable at that point. Patients are very confused about "same or similar" equipment in their home. For example, a patient could very easily have purchased a standard wheelchair (capped at 13 months) and at a meeting of the American Association for Retired Persons (AARP), see a three-wheel scooter or even a lightweight wheelchair and ask their physician to prescribe it. A provider must be able to access the CWF to ascertain whether or not the patient is eligible for the second wheelchair so that the provider will be reimbursed.

In the case of oxygen, the Proposed Rule clearly outlines the few exceptions when a patient would be able to transfer to another provider. The receiving provider would need to know the actual number of months left in a patient's rental cycle in order to determine if they can afford to accept the patient on service since CMS would expect the receiving provider to supply new equipment, supplies and service upon the transfer (if under 36 months). Using the Morrison Informatics study data cited earlier, the average acquisition cost for <u>all</u> oxygen systems and accessories (excluding disposable supplies) in the home is $1,288.[18] In the example just described, if the patient was at 34 months of continuous use, the provider would receive two months' payment and yet be expected to provide $1200-plus of equipment, with service costs added to that, representing a financial loss that few providers would be willing to absorb.

[18] 67 Fed. Reg. at 8459.

The HIPAA privacy provisions describe the circumstances under which a HIPAA covered entity may disclose "protected health information" about an individual to a third party without the permission of the individual to whom the information relates. These circumstances include for purposes of treatment, payment, and health care operations. 45 C.F.R. § 164.506. DME supplier access to the protected health information of individuals to whom the supplier may furnish equipment falls within the treatment and payment exceptions and should be permitted.

Specifically, the Privacy Rule allows a covered entity to disclose protected health information for the treatment activities of a health care provider. The Medicare program is a HIPAA covered entity. DME suppliers that submit electronic claims are health care providers. A DME supplier that is considering furnishing equipment to a Medicare beneficiary is engaging in potential treatment activities.[19] Thus, the Medicare program is permitted, under HIPAA, to share with the DME supplier information about the patient's past treatment (*i.e.*, past equipment usage), in order for the supplier to determine appropriate prospective treatment efforts. We request that CMS accelerate this request.

CMS must clarify how a "break in service" applies to short-term or intermittent usage of home oxygen therapy.

The Proposed Rule does not address how a "break in service" will be handled in the future. There are a number of reasons why a patient may have a short-term need for oxygen and the rental month(s) should not be included in the period defined as "continuous use." Patients that fall within the Group II oxygen coverage guidelines may not be sufficiently hypoxemic to require ongoing oxygen therapy, although they might become a continuous oxygen therapy use oxygen patient at a later date. Their short-term use, *i.e.*, 30 to 60 days, should not be included in the 36-month continuous rental period if they return to oxygen therapy after a "break in service."

The "36-month clock" should start over in select situations.

The examples above provide ample justification for CMS to develop a clear policy that allows the "36-month continuous use clock" to start over if the patient transfers to another provider in less than 36 months in the case of oxygen, or less than 13 months in the case of capped rental HME. In addition, it shows the level of criticality in regard to providers need for access to the CWF no later than January 1, 2007.

[19] Treatment is defined as the ". . .provision, coordination, or management of health care and related services by one or more health care providers. . . " 45 C.F.R. § 164.501.

The title to the equipment should not transfer to the patient until payment has been made in full, including any patient co-pay or deductible amounts that are owed to the provider.

CMS and Congress routinely refer to the amount that both the Medicare program and beneficiaries pay in the form of monthly payments and the associated out-of-pocket expenses incurred by beneficiaries. Savings projections published by the same groups regularly include a reference to how much money beneficiaries will save as the result of various legislative or policy initiatives. Competitive bidding and the DRA are just two recent examples where such references to patient co-pays were made.

Therefore, we believe that title to the equipment should not transfer to the patient until payment is made in full for all services rendered through the 36th month. Typically, Medicare would pay the 36th month's rate approximately 30 days later. Apria and other industry members have proven to CMS in prior studies and even public financial disclosures required by the Securities and Exchange Commission (SEC) that there is a percentage of beneficiaries who simply do not pay their 20% co-pay amounts despite the fact that they do not qualify for a formal financial hardship waiver. After numerous attempts to collect the co-pay amounts, providers have to write off the 20% co-pay amounts as bad debt expense, which for Apria approximates 3.0%.

Thus, the 36-months (for oxygen) would not really be paid in full until the final payment is received from Medicare in the 37th month and all outstanding patient payments due for the 36 months are paid to the homecare provider, including outstanding deductibles.

We assert this position because the language of the relevant sections of the Act, as amended by the DRA, is not very clear or comprehensive when referring to 36 months of payments. We urge CMS to clarify this expectation in the Final Rule because nowhere in the relevant sections of the Act does it state or suggest that a beneficiary's failure to pay a copayment would mean that the section of the DRA implementing the title transfer requirement would not be applied with respect to that particular beneficiary until all payments are made. Yet, Congress and CMS constantly refer to the co-pay portion, and if CMS is not going to go on the record to clarify this issue, it could lead some patients to think that they are not accountable for their co-pay and thus providers could experience an even higher level of bad debt expense or write-offs. If this is not made clear, then essentially Medicare and CMS would be saying that providers are actually going to be assured of payment for only 80% of the total Medicare allowable over 36 months, which would then represent yet another reimbursement cut.

No other business in America would transfer title of products or equipment that has converted from a rental basis to a purchase until all applicable payments owed to the prior owner of those products or equipment are paid in full.

Medicare's proposal will not cover "routine maintenance" that has historically been provided by home oxygen providers. CMS and Congress are erroneous in assuming that frail, elderly oxygen patients will be able to perform such maintenance.

We understand from the Proposed Rule that CMS expects beneficiaries to be able to perform routine maintenance on their oxygen equipment and any DME in the home after they assume ownership of it.

However, Apria's experience suggests otherwise. A review of on-call data for 170 Apria branches from a two-month period in mid-2006 suggests that oxygen is the number one category and HME is the number two category that generate after-hours and weekend calls from patients, resulting in several thousand inbound calls for each category every single month.[20] Moreover, the number one reason for those calls is related to "Equipment and Service" (separate from any calls requesting information about the time of their delivery or calls from referral sources requesting that new patients be set up after hours or on weekends.) This means that patients experience an issue with their concentrator, liquid system or transfilling system and call Apria's 24/7 on-call service for assistance. Although a limited amount of troubleshooting may be done via the phone, which the OIG failed to recognize, the vast majority of the calls result in an Apria on-call employee visiting the home. Apria must pay employees a premium hourly rate to be on-call and/or perform in-home visits after hours, on weekends and holidays. If the patient's problem is simple, such as clogged oxygen tubing, a problem with the plug or a blocked external intake filter filled with cat hair, it is resolved by the Apria employee in the home with no claim billed to Medicare. Non-oxygen examples include problems with semi-electric or electric beds, their motors or other issues; noise levels from CPAPs or nebulizers or a problem with the air flow in such devices. In the current scenario, no charge is billed to Medicare because 1) We own the assets, and 2) The issue may be described as routine. If the equipment is malfunctioning, we simply provide the patient with another device (via an exchange) and again, since we own the assets, we have not historically billed Medicare for any repairs performed on the equipment. This happens routinely.

Even the OIG's Oxygen Report reinforced the point that a certain percentage of patients will not be able to perform what CMS has described as routine maintenance. In its Oxygen Report, the OIG stated that 50 percent of the service visits conducted through the surveyed patients included what has been described as "routine maintenance." This translates into a significant number of Medicare beneficiaries who require such help – perhaps as high as 500,000. Further, the OIG Oxygen Report stated that "only 6 percent of the concentrators used by sampled beneficiaries malfunctioned at any time during their rental period," [but] that equipment was exchanged on 8.3% of the patients sampled.[21] Again, these are substantial numbers because they translate into 60,000 and 83,000 patients respectively. If CMS expects home oxygen providers to continue to provide 24/7 on-call service and yet will not reimburse providers who assist patients in need of help, yet another access to care issue will occur.

Routine vs. Non-Routine Maintenance Must be Defined More Clearly.

The preamble to the Proposed Rule indicates that CMS plans to apply its existing policy with respect to coverage of maintenance and servicing of beneficiary-owned equipment. 71 Fed. Reg. at 44099. This existing policy, found in § 110.2 B of Ch. 15 of the Medicare Benefits Policy Manual, distinguishes between routine and non-routine maintenance.

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[20] Internal review of on-call incidence and service data, by product category, Alta Resources Report, May/June 2006.

[21] OIG Oxygen Report, at. 10-11.

However, "routine maintenance" and "non-routine maintenance" are not defined in the Act or in the applicable regulations. Therefore, CMS must even more clearly define the difference between "routine" and "non-routine" maintenance specifically for oxygen and capped rental HME. This was not as critical before the implementation of the DRA when less than 10% of beneficiaries owned a very small percentage of HME and none owned oxygen equipment, but it certainly is important now.

The Rule is not clear on what constitutes "Routine" versus "Non-Routine" maintenance; different readers have interpreted the applicable section differently. To avoid any misunderstanding or miscommunication with patients, the agency and referral sources, we request that CMS define these two categories in the Final Rule so that there is time to develop communication materials before implementation.

For oxygen, we recommend that CMS define routine and non-routine maintenance as follows:

Routine Maintenance

- Wiping down outside surfaces of oxygen devices
- Removing, cleaning and replacing the external cabinet filter
- Changing oxygen tubing per Best Practices frequency schedule (two times per month)
- Cleaning, disinfecting and replacing oxygen humidifier bottles, if applicable

Non-Routine Maintenance

- Oxygen purity testing that requires an oxygen analyzer device
- Inspection of internal components for dust, debris and evidence of wear
- Changing of internal flow and regulator flow bacteria filters
- Cleaning of internal heat dissipation coils
- Any service or maintenance that requires breaking internal seals. This includes sieve bed assessment and repair, compressor assessment and rebuilds, electric motor assessment and repair, etc.

ACTUAL PATIENT EMAIL COMMUNICATIONS

The following email from a patient illustrates why the repair definitions and responsibilities for all HME and oxygen products need to be better defined by CMS:

Reference Number: 43884
09/15/2006 10:59 AM

Assigned To: Brian Geshel
Assignment CC: Barbara Underwood
Category: Customer Service
Status: Complete
Readers: Brian Geshel, Barbara Underwood

City: Marquette
State: Michigan
Region: Upper Midwest
Division: Central

Subject: Sleep Apnea Machines

A person who has one of your machines had an incident with her machine at a hotel It was accidently knocked over and water got into the motor. My question is, is something like this repairable or is it better to buy a new machine?

I just need some clarification and hope you can help me.

Thank you.

Patti S.

Since the publication of the Proposed Rule, we have received guidance that suggests that CMS would reimburse providers for "more extensive maintenance which, based on the manufacturers' recommendations, is to be performed by authorized technicians and is covered as repairs for medically necessary equipment which a beneficiary owns." The preamble indicates accordingly that "(a)ll non-routine maintenance of beneficiary-owned oxygen equipment...which would need to be performed by authorized technicians would be covered as reasonable and necessary maintenance and servicing" 71 Fed. Reg. at 44099.

This is a step in the right direction, however, it is very difficult to comment specifically on this topic since we have no idea what the payment rates will be. The average cost of an in-home visit by a non-clinician is $42 per the Morrison study before other overhead costs are applied. We are concerned that CMS' plan for establishing an appropriate rate have not been well-researched.

After the 36th month for oxygen and 13th month for HME, if "routine" maintenance is not covered in any way by Medicare and is therefore not a covered benefit for patients who take ownership of their equipment, providers who choose to offer such a service will be entitled to bill the beneficiaries directly for a non-covered service. Providers will be expected to be paid for those services at the time they are rendered. Patients will need to pay out-of-pocket via credit card, personal check or cash.

Below is a real example of a patient who requires assistance after taking ownership of his CPAP and would like a newer model.

Reference Number: 44011
09/23/2006 07:18 AM

Assigned To: Janet Hunt
Assignment CC:
Category: Customer Service CPAP
Status: Open
Readers: Janet Hunt

City: Lake Forest
State: California
Region:
Division:

Subject: cpap machine [Possible Spam]

to whom it may concern:

I have a cpap machine that was prescribed for me for sleep apnea and sent to me by you. It is very big and very uncomfortable. I own the machine.

my physician, dr. gaglairdi, suggested that I start using the machine again, but I am unable to.

is there anyway that you can replace this old machine with a newer model?

CMS Must Establish Standardized Allowables for Repair Parts, Labor and New Maintenance Rates Described in the Proposed Rule.

We suggest that CMS standardize its repair and maintenance policies, coverage guidelines, HCPCS codes for repair parts and labor, and update this schedule regularly. The Medicare allowables for repair parts and labor are not standardized. Each DME MAC creates its own interpretation of the repair policy and guidelines. In fact, in a telephone survey conducted by Apria Healthcare in September 2006 in which all of the three DME MACs and the fourth DMERC were contacted to ascertain reimbursement information for billing repairs, four different responses were given. It concerned us that Region D/CIGNA could not even provide a Medicare allowable for repair in any individual state contained in the Region. Apria was advised that "individual consideration" would be given for repairs.[22]

This kind of inconsistency cannot continue once patients assume ownership of their HME in 2007 and oxygen in 2009. Because the Proposed Rule did not include a definitive fee schedule or methodology for either repair or non-routine maintenance of patient-owned equipment, we are unable to comment more concretely in terms of whether Apria will be able to perform such services in the future.

[22] Telephonic survey between Apria Healthcare's Regulatory Compliance Department Managers and DME MAC representatives in all four DME MACs, September 2006.

We urge CMS to implement one consistent national policy and fee schedule that is eligible for either a Consumer Price Index (CPI) or Medicare Economic Index (MEI) adjustment annually. The fee schedule should also reflect the fully-loaded costs of providing repair, not just repair parts and labor. The Morrison Informatics study demonstrates that the average range of costs for the in-home visit alone is between $40 and $50 for non-clinical professionals during regular business hours, with a premium of 50% and 100% for after hours/weekends and holidays, respectively. Other costs that must be incorporated include office lease expense tied to the repair center, utilities, repair tools, calibration and testing devices, vehicle costs to and from the patient's home, labor, billing the Medicare program for the repair claim and collecting the co-pay from the patient.

CMS also has not considered the very common scenario associated with a provider that goes out of business, eliminates its repair function, goes into bankruptcy or is purchased by another provider. It is difficult to see how a provider that originally provided certain medical devices or oxygen could repair or assist in maintaining equipment if it is no longer in business or located in a particular town or area. That is another reason why it is so important for CMS to standardize its repair and maintenance policies, coverage guidelines, HCPCS codes for repair parts and labor and update the schedule regularly. If this is not done, few providers that were not the original suppliers of a patient's medical devices will be inclined to repair or maintain equipment that it did not supply in the first place.

The Proposed Rule is silent on how CMS expects homecare companies to respond to patient or physician requests for certain services after the medical devices cap.

Services other than delivery are inherently provided to patients as part of the monthly bundled rate for oxygen and DME. The best examples are 24/7 on-call services, emergency/weekend response and an in-home patient assessment performed by a state-licensed clinical respiratory therapist for oxygen, CPAP or Respiratory Assist Devices (RADs). Today, this assessment is conducted with a valid physician's order, and the results are sent back to the physician in the same manner as a lab test would be. After the 36th month, this service could not be provided to patients unless a HCPCS code is created and an allowable developed, due to the fact that its value exceeds what would be considered acceptable by the Office of Inspector General (OIG) in terms of the Beneficiary Inducement Statute (BIS).

The Proposed Rule is completely silent on several key aspects of homecare services provided to beneficiaries, such as the following four examples:

1. How to handle manufacturer product recalls after the patients assume ownership of their medical devices,

2. How CMS will address patients' previously inalienable right to switch providers if dissatisfied,

3. How CMS expects providers to coordinate services for patients who travel after they have purchased the equipment. Today, all services are coordinated for the patient by the homecare provider and they are technically reimbursed under the monthly bundled payment rate, and

4. How in-home clinical patient assessments performed by licensed respiratory therapists, according to written or verbal orders issued by a licensed physician to conduct such an assessment, will be reimbursed for oxygen patients who exceed the 36th month but still require such service.

THE FOLLOWING ACTUAL PATIENT COMMUNICATIONS ILLUSTRATE A FEW OF THESE CHALLENGES:

Reference Number: 43476
08/23/2006 06:55 AM

Assigned To: Derek LaFontaine
Assignment CC: Steve Gradwell
Category: Traveling with Oxygen
Status: Open
Readers: Derek LaFontaine, Steve Gradwell

City: Kennewick
State: Washington
Region: Northwest
Division: Western

Subject: travel certificate sent to northwest airlines--leaving this Friday flight 811

PLEASE SEND COPY OF DR.S ON-GOING ORDER FOR O2. I WILL BE GOING TO ANN ARBOR AND THE AIRLINE WILL SUPPLY THE AIR IN FLIGHT I CAN USE MY REGULATOR AND CANNULA. THIS IS SUDDEN BUT MY DAUGHTER IS PREGENANT AND VERY ILL, THEY WILL BE INDUCING HER ASAP. I HAVE BEEN USING THE WASHINGTON OFFICE IN OLYMPIA I BELIEVE, BUT THE KENNEWICK,WA OFFICE ALSO HAS ALL OF THE INFO, ALL YOUR PEOPLE ARE SUPER....THANK YOU SO MUCH...YOU CAN FAX TO MY HUSBANDS TRAILER, I AM STAYING HERE IN WOODBURN UNTIL FRIDAY, FAX NO.503-981-0334. I WILL BE ON MY CELL PHONE,360-XXX-XXXX.THANK YOU AGAIN, I KNOW IT IS SHORT NOTICE, JULIA G.

Reference Number: 43485
08/23/2006 01:24 PM

Assigned To:
Assignment CC:
Category:
Status: Open
Readers:

City:
State:
Region:
Division:

Subject: Request for procedure and information

Dear Sir/Madam:
My husband uses APRIA services for oxygen in Aurora, Colorado but he will be traveling to Mesquite, Nevada for a week starting 9/5/06 and will require oxygen supply. How do I go about getting the oxygen supply from St. George's, Utah?
Thank you for your courtesy and assistance.

Reference Number: 43472
08/22/2006 09:33 PM

Assigned To: Janet Hunt
Assignment CC:
Category: International- Supplier (Mexico)
Status: Complete
Readers: Janet Hunt

City: Lake Forest
State: California
Region:
Division:

Subject: liquid oxigen

MY NAME IS CONNIE D, I AM USING LIQUID OXIGEN AND MY DOCTOR SAID I CAN FLY.
I WANT TO GO TO MEXICO, LA PAZ IN OCTOBER, I WOULD LIKE TO KNOW ANY INFORMATION IN GETTING OXIGEN THERE.
SINCERELY,
CONNIE D.

After the final rule is published, CMS must issue clear direction to DME MACs and the DMERC regarding the provisions in order to avoid a sharp, unwarranted increase in post-payment audits for providers who are trying to navigate through the new rules.

As described in the "Background" section of the Executive Summary, Apria Healthcare has a strong Corporate Compliance program and has been recognized nationally for its ethical and compliant business practices. Our size, however, does cause Apria to be the subject of a high volume of post-payment audits, with which we comply completely through our Regulatory Affairs and internal compliance audit departments. This is frustrating since our track record for complying with audit requests and producing the requested documents is good, while smaller providers whose claim volume is less may never be audited. (As a company that acquired a large number of small and medium-sized providers in recent years, we have recommended to CMS and the Program Safeguard Contractors that they change their audit selection methodology to include small and medium providers in terms of claims volume.) We are concerned that if CMS does not provide enough specific guidance to the DME MACs and providers about certain aspects of the Proposed Rule, the volume of post-payment audits could increase. For example, the definition of "Change in Medical Condition" related to a change in oxygen equipment a patient requires absolutely must be clarified in the Final Rule. Access to the CWF must be given to providers in order to avoid a large increase in the level of denials related to "Same and Similar Equipment."

Providers should not be subject to post-payment audits and possible recoupment action after the title transfers to the patients. The same recommendation applies to recoupments tied to patients who enter Skilled Nursing Facilities (SNFs) for a month or more. It is CMS' responsibility to ensure that the DME MACs are current with their audit activity within the period of continuous use.

Transferring ownership of medical devices to the general public is fraught with operational, patient care, public safety, legal and reimbursement problems.

While Congress' intent to give patients more "control" over their DME and oxygen equipment sounds reasonable on paper, it is important to note that patients have not asked for such control, as evidenced by the fact that less than 10% have elected the purchase option available for Medicare capped rental DME in the past. As the industry has already expressed through the formal comments submitted on the competitive bidding rule, patient and public safety issues have not been addressed in the context of a large volume of patient-owned equipment. To our knowledge, the FDA has not been consulted or commented publicly on the safety aspects associated with patient ownership of oxygen cylinders that are regulated by its Medical Gas division (along with the DOT, Department of Homeland Security, Federal Aviation Administration and Transportation Safety Administration). In recent month, a limited number of used medical devices (either discarded inappropriately, stolen or in limited circumstances patient-owned (such as managed care patients whose payor has bought them a nebulizer or CPAP) have been sold at garage sales, flea markets, via the Internet and eBay. Sellers often promote the original DME providers' name and describe the products as "lightly used" or "as is." They make no guarantees or warranty transfers to the buyer. There is no description of any preventive maintenance that may have been performed by the seller.

We are very concerned about CMS' and Congress' assumption that patients will welcome the opportunity to perform maintenance and service on their medical equipment. The data we have provided elsewhere in this document about the nature of on-call requests from patients demonstrates that a large percentage of patients simply do not take an active role in troubleshooting or maintaining their equipment even on a basic level. When filters are clogged in oxygen devices, for example, the purity level of oxygen they would produce is compromised and the patient would therefore not be adhering to the physician's prescription regarding a specific liter flow or purity level.

Homecare providers have confronted eBay sellers who are selling stolen or inappropriately sold equipment. The seller usually states that he/she bought leftover equipment at an elderly neighbor's garage sale, or they retract the sale if they cannot produce a valid receipt to the provider's Legal Counsel. The government agencies that regulate medical devices and oxygen (listed above) have no idea of the amount of medical devices and oxygen cylinders being shipped around the country and sold to unsuspecting buyers in an unsafe fashion.

The DRA also requires patients and their families to dispose of their used equipment properly and safely. Today, the patient or family simply calls the homecare provider to retrieve the equipment that is no longer needed or being used and the provider picks it up because the item is under a rental agreement. Improper disposal of certain medical devices could lead to a public safety hazard.

In addition, the potential for the spread of infection is highly likely. The general public does not have the knowledge or expertise to properly disinfect this equipment prior to selling to other members of the public. Transmission of respiratory pathogens in the internal filters of oxygen equipment, or other pathogens found on hospital bed mattresses, is highly likely if the product or device is not properly disinfected between patient uses. Today, accredited providers who comply with the infection control requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other accreditors perform these functions correctly.[23] The "new" patients who buy used products/devices would lack the necessary training and knowledge for their safe use and operation, creating potentially dangerous situations. Today, HME providers are responsible for the traceability of these devices into specific patient homes in the event of medical product updates or recalls. Once the patient takes ownership and the title transfers, many of these devices will no longer be able to be tracked for recall purposes, especially following a subsequent garage sale after the patient's death. There are two such active product recalls affecting capped rental HME equipment underway as of this date, and the reason for the recall is related to mitigating risks to patient safety.

Oxygen, and medical devices responsible for the generation of oxygen, their preparation, preparation and transportation are heavily regulated by the FDA and DOT. Therefore, any oxygen-related equipment or device requires special consideration and safety guidelines to prevent catastrophic results to the general public. Patient-owned medical devices will provide significantly less control over potentially explosive technologies.

We urge CMS to cooperate and coordinate with the FDA to develop standardized guidelines that apply specifically to the public's resale of used medical devices as a result of the transfer of ownership provision of the DRA. CMS should not be dismissive about the issue of oxygen cylinder ownership and must confer with the FDA's Medical Gas division experts to review the impact of this specific law and on the Proposed Rule. In addition, CMS and the FDA should discuss the ability for medical oxygen fillers to comply with 21 CFR 210 and 211 once the patients own their own devices and equipment, including the

[23] Joint Commission on Accreditation of Healthcare Organizations Standards Manual for Home Medical Equipment Providers, 2006. Sections on Infection Control, Quarantine of Clean/Dirty Equipment and Patient Safety Goals.

portable oxygen cylinders that are operationally fungible for most home oxygen providers. If necessary, the Federal Trade Commission (FTC) must be consulted as well in order to stop eBay and other on-line marketplaces from selling medical equipment that may only be sold or dispensed to a specific patient based on a licensed physician's prescription.

ACTUAL EMAIL SHOWING UNREGULATED SALE OF USED OXYGEN CYLINDERS ON eBAY

Reference Number: 44021
"eBay member: on 09/23/2006 09:41 PM

Assigned To:
Assignment CC:
Category:
Status: Open
Readers:

City:
State:
Region:
Division:

Subject: RK sent you this eBay item: Medical Oxygen Cylinder - Lightweight Aluminum, "D" Sz.

(See next page for eBay ad)

Medical Oxygen Cylinder - Lightweight Aluminum, "D" Sz.

Current bid:
US $4.50 (0 bids)

Buy It Now
US $17.50 (immediate payment required)

Shipping:
View Item to Calculate

End date:
Sep-26-06 15:51:37 PDT

Add to watch list | See similar items

Find out more

View This Item

Details for item number: 190034282922

Item URL:

http://cgi.ebay.com/ws/eBayISAPI.dll?ViewItem&item=190034282922&ssPageName=ADME:B:EF:US:11

Description:

Medical Oxygen Cylinder You are bidding on a used but extremely nice re-fillable medical oxygen cylinder. Virtually new, as show

Ships to:
N. and S. America, Europe, Asia, Australia

Seller:
100% Positive Feedback
Member since Mar-20-02 in United States

5. Impact of Proposed Rule on Patients and Physicians

Patient choice of oxygen modalities and providers is restricted.

Patient preference and choice of oxygen modalities, which have historically been accommodated by providers for quality patient care and competitive reasons, will be severely restricted for all oxygen patients, and all but eliminated for patients who exceed the 36th month of continuous use of oxygen. The Proposed Rule allows only four exceptions, including a change in medical condition. However, the Proposed Rule does not define a change in medical condition or provide enough detail to understand how and when patients will be entitled to switch oxygen modalities, how that will be documented so that providers will be paid appropriately and promptly. Patients who move or choose to switch providers due to dissatisfaction with their service will also experience an access-to-care issue, since few providers will accept such a patient if he/she has only a few months left on the rental schedule but would be expected to provide oxygen equipment, including the back-up and other unreimbursed equipment. The provider will be placed in the middle of this situation.

To illustrate the role of patient preference, we have included several actual email inquiries that were sent to Apria's web site in recent months.

Reference Number: 43879
09/15/2006 07:26 AM

Assigned To: Kathleen Caldwell
Assignment CC: Steven Clark
Category: Traveling with Oxygen
Status: Complete
Readers: Michael Marino, Steven Clark, Kathleen Caldwell

City: Charlotte
State: North Carolina
Region: Carolinas/Tennessee
Division: Eastern

Subject: Portable Oxygen Concentrators

I live in Charlotte, NC and would like to travel by car to Austin, TX.
My question is how to handle that since I am on oxygen therapy.
Do you have portable concentrators?
Do you have concentrators that can be used through an outlet in the car?
Can I exchange tanks for refills along the way?
How dangerous is it to travel with oxygen tanks in the car?

I am currently with another supplier but would consider changing if your company has the ability to make our travel easier.

Charles P.

Reference Number: 43919
09/18/2006 04:31 PM

Assigned To: Steve 'Branch Mgr' Simmons
Assignment CC: Steven Clark
Category: Customer Service
Status: Complete
Readers: Janet Hunt, Steve 'Branch Mgr' Simmons, Steven Clark

City: Jackson
State: Tennessee
Region: Carolinas/Tennessee
Division: Eastern

Subject: Question

Today we had our first regular service call and the young fellow was just great-believe his name was Brennan=but you can can check this out. We travel a lot, many times via auto and he mentioned that there is a smaller concentrator available for travel purposes. Sure would make it easier to transport. We gave him dates that we needed one and would arrange for it-I will followup.

Now my question-We do travel via auto quite a bit and many times on impulse (retirement has its benefits) and I thought it would be great to have a small unit available to us, in addition to the current concentrator I have. I do not want to pay more-does Medicare cover an additional unit?? I would be willing to give back some of the current equipment we have-like two big tanks in case of power failure

Frank S.

Reference Number: 43899
09/17/2006 06:12 PM

Assigned To: Janet Hunt
Assignment CC:
Category: Customer Service CPAP
Status: Complete
Readers: Janet Hunt

City: Lake Forest
State: California
Region:
Division:

Subject: equipment available? [Possible Spam]

To Whom It May Concern:

I have been using a CPAP since about October of last year and have tried several different masks but have found none that are comfortable enough to allow me to sleep through the night. My doctor prescribed the ComforCurve by Respironics Is there a website I could visit or a brochure you could send me of what Apria has available so I might see this mask? I am desperate for a good nights sleep.

Thank you for your time.

Becky H.

Reference Number: 43328
08/14/2006 07:36 AM

Assigned To: Christina Thomas
Assignment CC:
Category: Customer Service
Status: Complete
Readers: Christina Thomas

City: Lake Forest
State: California
Region:
Division:

Subject: understanding different portable units

Dear Apria –

My mother is on oxygen 100% of the time and I'm trying to understand the different portable units that are available so that I can help advise her as to what she may need. I am going to be moving this fall and will want her to be able to come visit on a regular basis. We have been told that we can have a concentrator unit put in my home free of charge to have available for her when she visits. My question is for her travel time and if we want to travel somewhere in the area away from her home what is available for her then? She has the small light tanks presently that she fills up from her nurse tank at home but those of course do not last long so that would not be an option unless a nurse tank could also be delivered to my home. Is that an option? If not – what do we use and what are the costs. What does Medicare cover? I have called the local place where she obtains her oxygen but I don't entirely understand what they are telling me so that is why I'm contacting you. Maybe you have some information that you can send me so that I can understand the portable units better? Thank you very much.

C.K.

Reference Number: 43979
09/21/2006 01:30 PM

Assigned To:
Assignment CC:
Category:
Status: Open
Readers:

City:
State:
Region:
Division:

Subject: AirStep Free Style

I am on oxygen and want to a light weight portable system for out of home activities.
--
D.B.

Reference Number: 43445
on 08/21/2006 02:25 PM

Assigned To: Jeannine Delivron
Assignment CC: Scott Sasserson
Category: Customer Service
Status: Open
Readers: Jeannine Delivron, Scott Sasserson

City: Cromwell
State: Connecticut
Region: New England
Division: Eastern

Subject: information

My mother is a client with Apria respiratory care I am her daughter and help her with her care. My question to your company is if you can provide her with a catalog of carrying cases that will hold her small travel oxygen tubes. I would also like to know if you have any coil type tubing instead of the straight tubing.

Thank you ,
Sharon G.

Physician preference related to oxygen modalities and providers is limited.

A change of oxygen modality requested by a physician for reasons other than a "change of medical condition," which historically has been accommodated by providers for the same reasons as above, will also be restricted. In addition, a physician's ability to assist the patient in switching providers will be restricted, since few providers are going to choose to accept a transferring patient on to service if there are only a few months' rental left for the patient.

6. Overlap and Conflict of Certain Provisions of the DRA with Competitive Bidding

Very little consideration has been given to the extent to which the provisions of the competitive bidding program and the DRA's provisions conflict with each other.

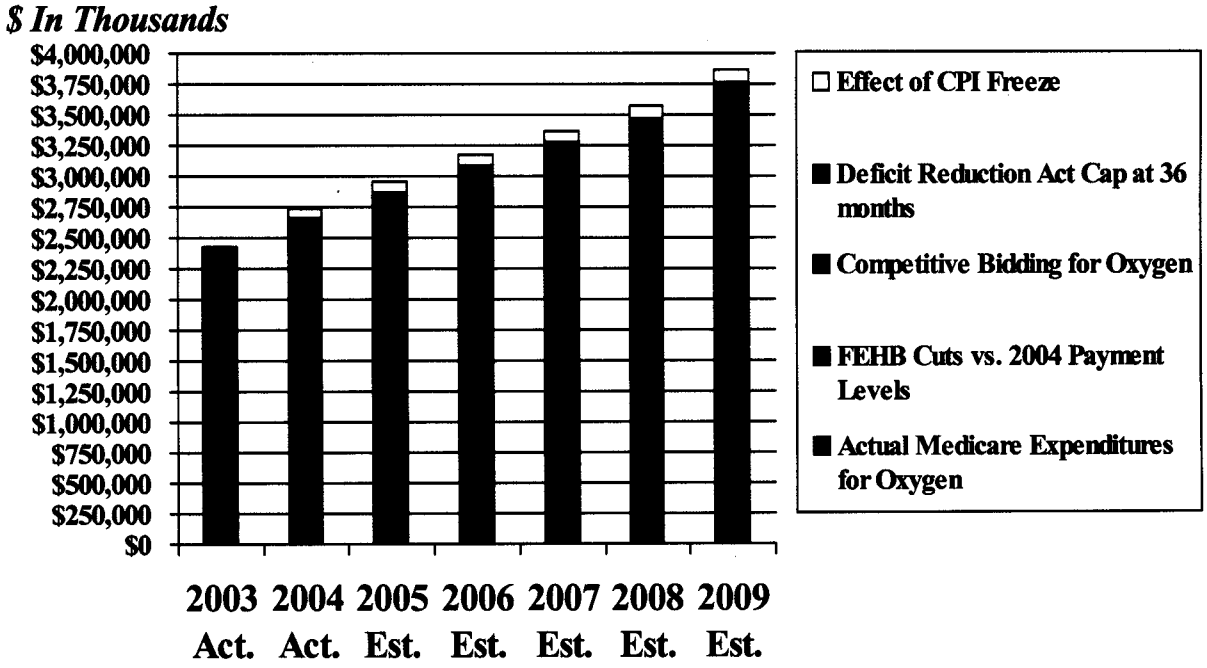
Specifically, the projected savings from the individual laws or programs are being double-counted on the Hill via the Congressional Budget Office (CBO) and by CMS. In addition, savings for competitive bidding have not been adjusted for the effect of the MMA-mandated pricing adjustments to oxygen and certain other DME items in accordance with the fee schedules associated with the Federal Employee Health Benefits Plan (FEHBP). That pricing adjustment resulted in an average 8.3% price reduction for oxygen, and reductions of more than of 25% for certain other HME. In addition, now that the DRA will reduce capped rental from 15 to 13 months, and eliminate the semi-annual service and maintenance fee, the government will again achieve additional savings that were previously counted in the competitive bidding savings estimates. Finally, the 36-month cap on oxygen will also afford significant savings to the program starting in 2009, leaving very little left in the form of savings to be generated by competitive bidding.

The following chart illustrates this point. Using actual CMS data for Medicare oxygen expenditures in 2004 as a base year and applying a normalized growth rate of 6%, the chart shows how Medicare will have achieved significant savings in the oxygen category as a result of both the MMA and the DRA. While competitive bidding was originally projected to achieve 20% of savings in the oxygen category, the MMA's FEHBP provision actually reduced payments by approximately 8.3% starting in April 2005, while the freeze in the Consumer Price Index (CPI) achieved approximately 3.1% starting in January 2005. Accounting for the FEHBP rates, savings from competitive bidding for oxygen in 2007 and future years are less than originally estimated after they are calculated off of the 2006 run rate. The DRA's 36-month cap affords CMS with the largest savings, starting in 2009 when the 2006 patients who reach the 36th month continue on oxygen service.[24] **Thus, all of the savings planned for competitive bidding (and possibly more) will essentially be realized by the FEHBP and DRA provisions.**

[24] This assumption does not reflect any proposed changes set forth in the Proposed Rule since the rates are not yet finalized.

Cumulative & Trended Effect of Medicare Oxygen Cuts, 2004-2009*

2005: Assumes FEHBP Cut of 10% Applied in 2005 for three quarters, CPI freeze of 3.1% and $2.6B expenditures per CBO
2006: Assumes full year effect of 10% FEHB cut, CPI freeze of 3.1% and 6% historical growth
2007-2009: Assumes 6% historical growth year over year, CPI freeze of 3.1%, FEHB effect and cuts noted below



**Estimates for competitive bidding are based on CMS' proposed rule, list of top MSAs, an initial start date of Q4 2007, estimated portion for oxygen spending in each MSA and 10% estimated net savings in each MSA per CMS' Regulatory Impact Assessment. However, does not account for possible 2007 change in oxygen fee schedule as proposed by CMS in its rule published in July 2006. Deficit Reduction Act estimate uses CMS' data that 36% of oxygen patients exceed 36 months on service and applies that to 2008's Medicare oxygen estimated billings.*

CMS should clarify regulations that conflict between the Proposed Rule on competitive bidding and this Proposed Rule regarding the DRA.

Plans for DMEPOS competitive bidding (and the savings that have been ascribed to those plans) and the implementation of the DRA have not been adequately evaluated or reconciled. One significant area of concern related to patient access to care after both laws or rules take effect is exemplified by the following real-life example:

- Provider A is taking care of a patient with oxygen and the patient has used the oxygen for 30 continuous months prior to the "go-live" date of competitive bidding in a given market.
- Providers A and B both bid on competitive bidding in the market.
- Provider B is awarded the competitive bidding contract. Provider A does not win the bid and does not want to grandfather the patient. Provider A is entitled to retrieve its equipment because it is less than 36 months and the title has not yet transferred to the patient.

- Why would Provider B want to accept the patient on to service if there is only six months rental left in the 36-month maximum rental period? That provider would have to supply the transferring patient with all-new equipment and supplies that could average over $1,000 in total costs for the equipment alone and an average of $870 in non-equipment service costs.[25] Yet, Provider B would only receive six months of rental payments, and therefore lose money on the patient.

- **RECOMMENDATION: CMS must allow the "36-month clock" to start over again <u>whenever</u> a patient switches oxygen providers if less than 36 months of continuous uses have transpired.**

7. The Proposed Rule Presents Legal Concerns.

In addition to the issues previously discussed, Apria is concerned that the Proposed Rule presents other legal concerns that CMS has not yet thoroughly considered and we recommend the following:

- The Proposed Rule implies that a provider is obligated to repair equipment after title transfers. CMS should not require this given the lack of statutory basis for such a requirement.

- CMS should standardize its repair and maintenance policies, coverage guidelines, HCPCS codes for repair parts and labor, and update its schedule regularly using a CPI or Medicare Economic Index (MEI) factor;

- CMS should not require providers to replace patient-owned equipment;

- CMS should conduct further research to determine the average useful life of medical equipment, rather than applying an unsubstantiated assumption of five years.

- CMS should not require providers to commit to accepting assignment for 13 months (DME) or 36 months (oxygen) and alter dramatically the currently existing Medicare policy on assignment.

- CMS should not obligate providers to accept additional legal liability for patient-owned equipment that may not be maintained properly by the new beneficiary owner.

Repair, Maintenance and Replacement of Patient-Owned Equipment

We understand and fully agree with the fact that the Medicare supplier standards require a DME supplier to undertake certain repair or replacement activities for items that the supplier is <u>renting</u> to a Medicare beneficiary. Specifically, the supplier must:

> maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items that it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced.

[25] *Id.*, at 17.

42 C.F.R. § 424.57(c)(14). To be clear, this directive only applies to items that the supplier owns and is renting to the beneficiary. We are unaware of any historic statutory directive requiring a supplier to repair beneficiary-owned items. This is especially true in months 37-60 for oxygen, and in the interval between the 14th month and the 60th month in the case of capped rental DME.

The DRA requires that, after title transfer, Medicare continue to make payments for certain "reasonable and necessary" maintenance and servicing for parts and labor that is not covered under a manufacturer's or supplier's warranty. DRA § 5101(b); SSA § 1834(a)(5)(F)(ii)(II)(bb). The statute is silent about who may undertake these maintenance and service activities. Notably, there is nothing in the statute to suggest that the supplier who initially furnished the equipment would be held responsible for furnishing these services after title to the equipment is transferred to the beneficiary.

CMS appears to intend to permit a beneficiary to obtain repair services wherever appropriate. In fact, CMS expresses a lack of concern about the ability of beneficiaries to obtain service on beneficiary-owned equipment because it is not "aware of instances beneficiaries have encountered problems finding suppliers to provide maintenance and servicing of beneficiary-owned DME." 71 Fed. Reg. at 44099. This statement suggests that CMS anticipates beneficiaries may look to any source for repair and maintenance, not necessarily the original supplier.[26]

However, CMS has overlooked a critical data point when making this statement. Under the historical payment methodology for home medical equipment subject to capped rental, less than 10% of all Medicare beneficiaries have elected to purchase their medical devices such as nebulizers, continuous positive airway pressure (CPAP) devices, hospital beds, patient lifts or wheelchairs. No one has ever elected to purchase oxygen medical devices since that has not been an option under the historical payment method for oxygen; therefore, claims for repairs of patient-owned equipment would not have been prevalent in the existing Medicare database.

CMS does not have the statutory authority to require providers to replace patient-owned equipment.

Again we are referencing CMS' implicit proposal that providers replace patient-owned equipment in months 37-60 for oxygen devices and months 14-60 for capped rental HME. Providers are naturally concerned that they would be required to replace equipment that may not have been maintained as the providers would have maintained them.

There is no statutory requirement for a supplier to replace an item of beneficiary-owned equipment. Section 1834(h)(1)(G) of the SSA permits Medicare payment for replacement of prosthetic devices when the condition of the prosthetic requires repairs that would be more than 60 percent of the cost of a replacement device or replacement part. This provision does not appear to require the supplier to furnish the item for free. Rather, it authorizes the Medicare program to make payment for a replacement item prior to the expiration of the item's "reasonable useful life."

[26] This also is consistent with CMS' approach to routine maintenance of equipment. In Chapter 15 of the CMS Benefit Policy Manual, CMS notes that routine servicing of beneficiary-owned equipment is the responsibility of the beneficiary. Furthermore, this activity may be undertaken by either the beneficiary itself, or the beneficiary may hire a third party. See CMS Benefit Policy Manual, Ch. 15, § 110.2.B ("...[h]iring a third party . . . for the convenience of the beneficiary ... is not covered").

CMS should reconsider the "Sixty Percent Rule."

In the Proposed Rule, CMS proposes that an initial supplier be responsible for furnishing replacement of beneficiary-owned equipment, at no cost to the Medicare program, if (i) the aggregate repair costs after transfer of title exceed 60 percent of the cost to replace the equipment and (ii) the equipment has been in use for less than its reasonable useful lifetime. ("Sixty Percent Rule").[27] While CMS is attempting to effect a noble policy goal of reducing the potential for abusive supplier behavior, there appears to be no statutory or regulatory precedent for this approach. The use of a 60 percent threshold only applies statutorily in the context of prosthetic limbs[28] and has never been defined in statute for DMEPOS. Using prosthetic limbs as an analogy to establish a policy for DMEPOS is invalid and not reflective of the homecare industry.

CMS has also not considered the situation where a patient owns a device or equipment, and when it malfunctions or is beyond repair, the patient then would like like the newer model – typically a much higher cost device with enhanced features - without any change in his/her medical condition. According to the Proposed Rule, the provider would likely have to provide it. Yet, 60 percent of the replacement cost of the original equipment or device could be significantly less than the actual acquisition cost of the replacement one.

Furthermore, the Sixty Percent Rule is an example of CMS' lack of concrete data to support its proposal. For all of these reasons, CMS should reconsider the Sixty Percent Rule.

CMS' use of the term "average useful life," and the default rate of five years for DME and oxygen medical devices is unsubstantiated and outdated.

CMS does not substantiate its use of certain terms such as "average useful life" and its definition of the default rate. The Proposed Rule implies that the average useful life of medical equipment is five years. To our knowledge, CMS has not conducted any independent laboratory studies or manufacturer surveys of DME or oxygen equipment to determine if the five-year "average useful life" is accurate or current. In fact, providers' experience demonstrates that certain products have a much shorter "average useful life" than the five-year default. For example, nebulizers, CPAP devices, certain oxygen devices and portable ventilators definitely have an average useful life that is much shorter than what CMS suggests. We recommend that CMS conduct further research into the true average useful life of any medical equipment that will be subject to such a provision.

Moreover, CMS appears not to have considered how patients will access repair services from their original provider in the following situations:

- Providers could change location or go out of business.
- Providers could be sold to another provider and close the original location.
- Providers could enter into bankruptcy or otherwise be unable to repair the equipment they initially rented and then transferred title to beneficiaries.
- Patients frequently move and take their equipment with them.

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[27] CMS has indicated that it is likely to measure "reasonable useful lifetime" from the date the equipment is delivered to the beneficiary, rather than the actual age of the equipment. In the Preamble to the DME supplier standards, CMS states that "it would be infeasible to review the prior rental history of individual items of equipment." 57 Fed. Reg. 57675, 57684 (Dec. 7, 1992). This approach, coupled with the proposed mandatory replacement obligation, could be onerous for a supplier.

[28] Social Security Act, § 1834(h)(1)(G).

Even if the original supplier still exists, under the Proposed Rule, a supplier's obligation to replace equipment will be dependent upon the repair quality and fees of a third party over which the supplier has no control. This is an unreasonable expectation and an untenable situation.

With respect to the CMS replacement proposal, it also is important to note the other operational challenges associated with the aggregate repair rule that must be addressed before CMS implements such a requirement. Today, most providers who manage in-house repair programs do not track repair cost data at the individual device serial number level. More sophisticated providers track repair using different metrics, such as employee productivity, repair volume by category or location, but they are not catalogued in most providers' information systems on a cumulative cost basis at the serial number level. Additionally, neither private nor government systems support the concept of accounting for cumulative repair costs at the serial number level. So, a significant amount of computer system reprogramming would have to occur before such a requirement could be implemented, and therefore we urge CMS to, at a minimum, delay this requirement.

CMS does not have authority to change Medicare assignment terms and should not require suppliers to disclose their intentions regarding assignment for the entire duration of the rental periods.

The Proposed Rule appears to require all suppliers, whether participating or non-participating, to "disclose to the beneficiary (their) intentions regarding whether (they) will accept assignment of all monthly rental claims for the duration of the rental period," which could be up to three years. 71 Fed. Reg. 44107. CMS cites as authority for this rule its general authority to administer oxygen payment rules at § 1834(a)(5) of the Act, and its general authority to administer the Medicare program at § 1871(a)(1) of the Act. Neither of these sections referenced by CMS mentions assignment or the conditions under which a supplier must accept assignment. For example, § 1871(a)(1) states: "The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title..." The approach of the Proposed Rule seems to be a requirement that suppliers become participating, at least on a patient-by-patient basis, with an assignment period that would exceed the one-year term imposed upon participating providers. This seems inconsistent with the Medicare assignment policy and its voluntary nature of accepting assignment on a claim-by-claim basis and the statutory limit of a one-year lock-in for participation decisions.

Current Medicare supplier standards require a provider to inform patients of whether or not it will accept assignment for one month at a time (per claim). It is unreasonable for CMS to expect a provider to commit to accepting assignment for 36 months when policies, payment levels or other things could change by the end of the first year. For example, if the physician writes a prescription for less than "lifetime" (*i.e.*, 12 months, if the patient is retested at the 12-month mark and no longer qualifies for Medicare coverage), the provider could not be expected to continue to accept assignment on the patient for the remainder of his/her time on oxygen. This is an everyday occurrence.

Under the Social Security Act (the "Act"), non-participating DMEPOS suppliers are allowed to accept assignment on a claim-by-claim basis. Social Security Act § 1842(b)(3)(B)(ii). CMS acknowledges this in the preamble to the Proposed Rule by stating that "Under Medicare, suppliers who furnish items of DME can accept assignment on all claims for Medicare services or on a claim-by-claim basis." 71 Fed. Reg. 44094.

The Act also allows suppliers the option of being a "participating" or "non-participating" supplier. A "participating" supplier is defined under the statute as one who "before the beginning of any year... enters into an agreement with the Secretary... to accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled (in Medicare) during such year." Social Security Act § 1842(h)(1) (emphasis added).

Thus, although being a "participating" supplier is voluntary, those suppliers that are "participating" are statutorily obligated to accept assignment on all claims for a period of the single calendar year.

In light of the lack of direct statutory authority, we presume CMS must be proposing something less than a binding agreement to accept or not accept assignment for the duration of a beneficiary's rental period, and that this expression of a supplier's intent could incorporate notice to beneficiaries of situations in which a supplier would decline to accept assignment during the applicable rental period. For example, it would be reasonable for a supplier to disclose to a beneficiary that the supplier *intends* to accept assignment on all claims for the duration of the rental period, but that the supplier would not accept assignment if, for example, the beneficiary moved or was no longer eligible for coverage or was abusing his/her equipment.

CMS claims that its intent in making its proposal is to provide beneficiaries with "advance notice of the possible extent of their financial liability during the period of medical need... so that they can use the information to help select a supplier." We understand this, but suppliers should be allowed to include in such advance notice descriptions of situations that would cause a supplier to change acceptance status during the period of medical need. Moreover, a supplier's obligation to agree to accept assignment for a particular patient, even if none of the triggering circumstances have changed, should not be required to last longer than a calendar year in order to be consistent with the limitations in the existing language of the Social Security Act.

The Proposed Rule is overreaching in terms of forcing the provider to accept additional legal liability for patient-owned equipment that may not be maintained properly by the new owner.

The Proposed Rule appears to obligate the provider to accept certain additional legal liability for patient-owned equipment that may n ot be maintained properly by the new beneficiary owner. While we believe the user manuals published by the manufacturers are helpful for patients to have as they maintain their equipment, dissemination of the user manuals does not relieve or address all of our concerns. Apria has researched the issue of legal liability for patient safety or similar issues that may arise after the transfer of ownership of the medical devices takes place. In the proposed service model where Apria participates with Medicare as a provider, rents medical devices to patients and then transfers title of the devices per the DRA, we understand that Apria could be considered a distributor in the chain of supply whether the DME is leased, sold, or otherwise transferred from Apria to the patient. See Rest. 3d Torts: Prod. Liab. § 20.

Consequently, we understand that providers may be subject to subsequent liability once the equipment leaves their control, even if the provider was attentive beforehand and appropriately maintained the equipment and instructed the beneficiary on its maintenance and correct usage. CMS appears not to have recognized this liability, risk and expense when calculating appropriate reimbursement rates.

CMS has also minimized the importance of routine maintenance for medical devices and underestimated the number of frail, elderly patients who will require assistance with even the most basic maintenance. Apria and other providers will incur additional, uncompensated administrative/overhead costs associated with this portion of the Proposed Rule.

8. Procedurally, the process undertaken by CMS to develop the rates recommended in the Proposed Rule do not conform to the requirements of the Data Quality Act (DQA).

Apria has substantial procedural concerns about the oxygen and oxygen equipment rules: namely, that CMS has not divulged either the underlying factual usage and budget data or provided a reasoned explanation of its budget projections, and thus Apria and other commenters are deprived of the right under notice-and-comment procedures to test CMS's claims of budget neutrality.

We do understand that in the context of a proposed rule-making, the application of a DQA challenge is limited and requires a party to participate actively in the public comment process. That is why we are providing extensive public comments on the proposed rule. However, the statute in which the DQA was included required the Director of the Office of Management and Budget (OMB) by September 30, 2001, to issue guidelines

> that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies . . . .

Under the statute, the OMB guidelines must require each federal agency to which the guidelines apply, in turn, to issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of its information, no later than a year after the date of issuance of the OMB guidelines. These agency-specific data quality guidelines must, among other things,

> establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the [OMB] guidelines . . . .

See Pub. L. No. 106-554, § 515 Appendix C, 114 Stat. 2763A-153 (2000) (uncodified).

CMS's data quality guidelines appear in the Department of Health and Human Services (DHHS) "Guidelines for Ensuring the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public." ("DHHS Guidelines") See http://aspe.hhs.gov/infoquality/Guidelines/index.shtml.

In its DQA guidelines, CMS has defined "influential scientific, financial, or statistical information" to be such information where "CMS can reasonably determine that dissemination of the information will have a substantial impact on important public policies or important private sector decisions or will have important consequences for specific health practices, technologies, substances, produces, or firms."[29] Influential information disseminated by CMS may include annual reports of the Medicare Board of Trustees and the annual publication of provider payment rates. Some of the data used in influential information disseminated by CMS is not distributed to the public since it is confidential. However, other information is based on publicly available data and is therefore reproducible.[30] The CMS guidelines indicate that transparency is achieved through the broad dissemination of its information.[31]

The Proposed Rule will have a substantial impact on public policies, patients, providers and referring physicians. Yet, there are numerous inaccuracies and a lack of objectivity in the Proposed Rule. Throughout the document, CMS uses the terms "we believe," "some believe," "we have heard" and other vague references to people whose expertise in homecare or patient care is unknown to the reader. These beliefs do not appear to be grounded in any clinical studies, market research studies, pilot studies or other data sources that might yield such information, nor are any materials referenced appropriately in a Proposed Rule of this nature. We saw no citations that physician, patient advocacy group, homecare provider or manufacturer interviews were conducted to support either the proposed payment rates for oxygen or certain proposed rules to which providers would need to adhere. No government cost studies or other data were cited to support CMS' many assertions about providers' costs to acquire certain oxygen modalities, perform service and maintenance or deliver portable oxygen. CMS's failure to provide such data violates notice requirements that ensure meaningful participation by the public, and constitute arbitrary and capricious decision making.

The CMS Guidelines also focus on transparency and reliability. This means that the data sets for producing estimates and projections must be clearly identified and documented. While some results may not be directly reproducible by the public because the data sets are confidential, the CMS Guidelines require confirmation by panels of independent technical experts. To our knowledge, there is no Technical Expert Panel (TEP) that has been convened by CMS to advise on the subject of home oxygen therapy coverage guidelines and payment levels, and industry stakeholders did not have an opportunity to participate in the Proposed Rule's development.

In accordance with the OMB Quality Guidelines, "influential" scientific, financial, or statistical information must be based on data and methodologies that can be reproduced. An example of how the data is not reproducible may be found in the percentage of patients on oxygen who exceed the 36th month of rental. In CMS' Proposed Rule, it states that this percentage is 36%,[32] while in the recently-published OIG Oxygen Report, the OIG states that it is 22%.[33] This is a tremendous data disparity that must be reconciled before moving forward with any oxygen payment or policy reform, since the assumptions or

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[29] *Guidelines for Ensuring the Quality of Information Disseminated to the Public: Centers for Medicare & Medicaid Services, available at* http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml (last visited Aug. 23, 2006).
[30] *Id. (*noting that where information is not reproducible by a third-party, more emphasis is placed on periodic review by outside panels of technical experts).
[31] *Id.*
[32] 71 Fed. Reg. at 44096.
[33] OIG Oxygen Report, at 8.

methodologies used by the two different groups appear to differ greatly, have not met the requirement of being "reproducible," and have very significant cost consequences.

Objectivity, which is also required as part of the DQA, concerns whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner and whether the information itself is accurate, reliable and unbiased. Agencies are required to provide information on the sources of the disseminated information as well as the supporting data and models in a scientific, financial or statistical context so that the public may question the objectivity of the data and sources.[34] Again, CMS has not met this requirement.

9. Concerns Regarding the September 2006 OIG Oxygen Report

We would be remiss if we did not include feedback to CMS on the recently-published OIG report on oxygen. Apria cooperated fully with the OIG by supplying survey data on a number of patients who were on our service in the survey year of 2004. In addition, the OIG Project Leader spent a full day in our Sacramento, California branch operation, observing first-hand the many operational, clinical, logistics, repair/maintenance, transfill center, billing/collection, customer service and other functions that are associated with the provision of home oxygen therapy. Her visits to Apria and other providers were an "eye-opening" experience in terms of witnessing the various services involved – all provided outside of the cost of the actual oxygen equipment itself. Yet, none of those observations were incorporated into the final report, leaving readers with numerous ill-informed impressions of the total cost of caring for Medicare oxygen-dependent patients at home.

We also find it curious that although the OIG study was initiated in the fourth quarter of 2005 with two clearly-articulated objectives: 1) to compare Medicare spending for oxygen concentrators with suppliers' average purchase price and 2) to determine the nature and frequency of servicing for concentrators and portable equipment,[35] the final report evolved into a commentary on the DRA's 36-month cap and repeatedly made reference to the cap. However, the DRA had not even been signed into law when the study was launched.

Regarding the cost comparisons outlined in the OIG report, we were very disappointed that the OIG repeatedly compared the average cost of an oxygen concentrator to a non-comparable value, that of how much Medicare spends over a 36-month period. CMS, the OIG and even the data found in the OIG report suggest that the average length-of-stay for Medicare oxygen patients is close to 18 months. Also, the OIG only collected cost data on concentrators; it did not study the acquisition costs of any of the other modalities currently used by Medicare beneficiaries, such as liquid oxygen, which costs providers 20 to 30% more than concentrators and 50 to 60% more in delivery costs. The OIG did not study the acquisition cost of portable oxygen concentrators (POCs) or transfilling systems, which both cost five to six times as much to procure than oxygen concentrators. Finally, the OIG did not study the cost of any of the other oxygen equipment or accessories that are inextricably linked to the safe provision of oxygen at home, such as regulators, oxygen conserving devices, flow meters, portable cylinders, cylinder storage racks for safety and back-up oxygen systems. (Only the regulator is currently recognized by Medicare by including it in an existing HCPCS code, and most patients request more than one regulator.)

[34] *Id.*, at 8459.
[35] *Id.*, at page i

Therefore, it is not surprising to us that the OIG's data analysis found that the average acquisition cost of an oxygen concentrator is $587,[36] while the Morrison Informatics report determined (using 2006 data) that the average cost for all equipment/accessories used at home, on a blended modality basis, is closer to $1,200.[37] Had the OIG's original survey asked for the total cost of such equipment/accessories, its final number would be quite different.

Additionally, the OIG report only studied a limited number of services related to the equipment and some maintenance, but it excluded other services that are provided to patients as part of the standard of care, regardless of their payor source. On page 6 of the report, the OIG states that it did not study any of the non-equipment services or service costs incurred by providers.[38]

Other data integrity issues exist with the OIG report, such as the report's assertion that oxygen cylinders are typically delivered to patients on a quarterly schedule.[39] Unless the patient sample were somehow slanted towards those patients who use oxygen only at night, there is a data calculation error. Even an informal survey of the home oxygen industry would reveal that the average number of gaseous cylinder deliveries per patient per month is 1.5 to 2.0, and for liquid portable oxygen the average is 2.0. The Morrison Informatics study reflects this reality with a blended rate of deliveries of 1.6 per patient per month.[40] The number of cylinders that would have to be delivered to the average oxygen patient if the schedule were every three months far exceeds what typical patients have room for in their homes. Another example of a data conflict is found in the OIG's report that 22% of all Medicare oxygen patients exceed the 36th month, while the Proposed Rule on which we are commenting specified 36% of the patients. This must be reconciled by CMS before moving ahead with any changes to the oxygen payment schedules.

Regarding the OIG's statement that providers are performing routine maintenance for patients who have been trained to perform the same, this only reinforces our view that a large percentage of Medicare beneficiaries simply cannot perform the routine maintenance on their oxygen equipment. They have memory, dexterity, vision, health and other issues that cause them to rely on their homecare provider for such services. Since providers are currently paid a fixed monthly rate from Medicare regardless of how much service or time they provide in the patient's home, one can only conclude that they are supporting patients' expressed needs by performing such routine maintenance.

The OIG's frequent reference to the 36-month cap and how much Medicare spends over that time period is very curious, since the DRA had not been passed when the study was initiated and the comparison is not listed in the study's objectives. The OIG should have reported on how much Medicare spends over the average of 18 months and included providers' total costs of providing oxygen services and equipment to beneficiaries over that time period, not the cost of the concentrator alone. Using the Morrison Informatics data to demonstrate the difference, it suggests that providers would incur approximately $1,000 in equipment costs and $2,617 in non-equipment costs to service the patients, for a total of $3,617. When one compares this to Medicare's and the patient's total expenditures over 18 months of $3,960, the difference is only $343. This reflects the operating realities for homecare providers and certainly does not warrant the type of inflammatory characterization that was found throughout the OIG report.

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[36] *Id.*, at page ii
[37] *Id.*, at page 17
[38] *Id.*, at page 6
[39] Id., at page 12
[40] Id., at page 20

The OIG also referenced the VA hospital contracting model in Florida. As a provider who contracts with the VA on a limited basis, Apria can state confidently that the VA model is completely different than Medicare's service model. The VA performs certain functions in-house that the Medicare model requires homecare providers to perform, such as respiratory therapist visits (the VA requires the patients to return to its facilities, while Medicare patients are seen at home), a simplified referral process by its own physician and clinical employees (compared to Medicare's more independent model with private physicians choosing the homecare provider they want to use) and billing. The VA also conducts a true competitive bidding program and guarantees the winning homecare provider both volume and exclusivity, while Medicare does not. The VA structures its contracts with the homecare supplier to include a la carte services with associated pricing levels, such as higher rates for liquid oxygen and per-cylinder rates for gaseous oxygen. There is no co-pay for VA patients, and the VA pays the contracted provider off of a spreadsheet that is submitted for all services rendered in the prior month.

The report referenced the Tampa, Florida VA facility and a comment about maintenance being performed annually. However, the Gainesville, Florida, facility contracts with a homecare provider for quarterly preventive maintenance and pays the provider accordingly. Lastly, the VA contract includes an automatic price increase every year the contract is retained by the incumbent provider, while the Medicare rates have been subjected to a CPI freeze since 2004.

By the time all of the a la carte services are bundled together and the VA's direct acquisition costs are accounted for, the total monthly payment allowed by the VA is either at or slightly above the current Medicare monthly bundled rate for oxygen therapy.

Finally – and perhaps most importantly – the VA does not cap oxygen reimbursement at any interval as long as the patient's medical need exists, and it does not transfer ownership of the equipment to the patients. Thus, the OIG's comparison of VA pricing to that of Medicare is grossly inaccurate.

For all of the reasons listed above, we respectfully request CMS to incorporate this feedback regarding the OIG study into its plans concerning oxygen payment policies. Relying on the report alone would cause a number of erroneous assumptions to be built into financial models and philosophical approaches to policies concerning reimbursement, repair/maintenance frequency and a delineation of the responsibilities of patients, physicians and homecare providers under the DRA, competitive bidding or any future umbrella.

----------END OF APRIA HEALTHCARE'S DETAILED COMMENTS----------