



July 25, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

*Re: CMS–6050–P: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items*

Dear Administrator Tavenner,

On behalf of the Council for Quality Respiratory Care (CQRC), I want to thank you for providing us with the opportunity to submit comments on the Proposed Rule entitled “Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items” (Proposed Rule).<sup>1</sup> The CQRC strongly supports implementing prior authorization for home respiratory therapy equipment, specifically related to home oxygen and home sleep therapies. We were disappointed that equipment for home oxygen therapies was not included on the Master List, particularly since the criteria for its inclusions as set forth in the Proposed Rule are met. Thus, we strongly urge the Agency to include home oxygen equipment on the Master List and subject these items, as well as home sleep therapy equipment, to prior authorization. We also support the Agency’s position that obtaining prior authorization would eliminate subsequent audits related to determining medical necessity.

**I. Home oxygen therapy equipment has inappropriately been excluded from the Master List even though it meets the criteria set forth in the Proposed Rule.**

The Proposed Rule indicates that the Centers for Medicare and Medicaid Services (CMS or the Agency) has relied upon objective criteria to establish the Master List for DMEPOS equipment from which equipment to be subjected to prior authorization will be selected. Home oxygen therapy equipment meets the criteria for inclusion on the Master List. First, home oxygen therapy equipment has an average rental fee of \$100 or greater on the fee schedule and in many Competitive Bidding Areas. When calculating the rental amount, we recommend that CMS also take into account how physicians prescribe the equipment. For example, the vast majority of physicians write prescriptions for home oxygen therapy patients that require suppliers to provide both stationary and portable equipment. Since audits are based upon the single prescription and the medical necessity

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<sup>1</sup>79 *Fed. Reg.* 30511 (May 28, 2014).

determination relates to that prescription, it would also be appropriate for CMS to evaluate the average rental cost for the total prescription when applying the payment threshold. We appreciate that CMS may not want to apply prior authorization requirements to supplies, but it is important to apply prior authorization in a manner that is consistent with how physicians prescribe equipment.

Second, these types of equipment have been the subject of the CERT Annual Medicare Fee-for-Service Improper Payment Report in 2011, 2012, and 2013 (oxygen equipment is on the improper payment list with a 75.6 error rate in the 2013 report),<sup>2</sup> as well as the subject of numerous GAO reports.<sup>3</sup>

The CQRC members agree that CMS should rely upon objective criteria to allow the Master List to be self-updating annually; however, the exclusion of home oxygen therapy equipment suggests that the criteria have not been applied in an objective manner. Given that home oxygen equipment meets the requirements set forth in the Proposed Rule, CMS should include this equipment on the Master List.

During the June 17 Open Door Forum, CMS suggested that one reason some equipment might not be included on the Master List is because it is subject to a special payment rule. If this concern is referring to 42 U.S.C. § 1395m, it is true that the title indicates that there are “Special Payment Rules for Particular Items and Services.” However, all DMEPOS items are subject to these payment rules. In addition, this section includes the payment structure for ambulance services, for which CMS has just established a pilot to implement prior authorization for certain types of transports. Clearly, the fact that the statutory authority for DMEPOS reimbursement is entitled “Special Payment Rules” cannot prohibit the Agency from implementing prior authorization for home oxygen therapy equipment. Whether or not items are subject to special payment rules has no bearing and, therefore, should not be considered as a criterion in developing a process aimed at identifying and preventing unnecessary utilization, which is inferred on the basis of prior payment experience.

## **II. Home oxygen therapy equipment, as well as sleep therapy equipment, should be on the Required Prior Authorization List.**

The CQRC strongly supports subjecting home oxygen equipment, as well as sleep therapy equipment, to prior authorization. The Proposed Rule is not clear as to what criteria CMS plans to use to select items that will be subject to prior authorization. We strongly encourage the Agency to establish objective, empirical criteria, not susceptible to qualitative adjustments or exogenous considerations. For example, an item with an error rate greater than 40 percent should be automatically included on the Required Prior Authorization List and remain there for at least the 10 years stated in the Proposed Rule. If the prior

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<sup>2</sup> See, e.g., U.S. Department of Health and Human Services, “The Supplementary Appendices for the Medicare Fee-for-Service 2013 Improper Payment Rate Report” (2013).

<sup>3</sup> See, e.g., GAO, “Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Supplies (Jan. 2007); GAO, “Medicare Program Integrity: CMS Continues Efforts to Strengthen the Screening of Providers and Suppliers” (Apr. 2012).

authorization initiative is successful, the Agency should consider maintaining the requirement permanently as well.

While the CQRC would like CMS to implement prior authorization as quickly as possible, our members believe it is important to provide an opportunity for notice and comment as to which items are on the Required Prior Authorization List. CMS should use rulemaking to provide for such transparency. For example, the Agency could issue an Interim Final Rule with a short comment period (*e.g.*, 30 days or perhaps less) that sets forth the Required Prior Authorization List and provides interested parties with the opportunity to comment. After reviewing the comments, if the Agency determines that equipment or items have been inappropriately included or excluded from the Required Prior Authorization List, these items could be added or deleted through a subsequent modification to the Interim Final Rule. Given the importance of this issue, the Agency should provide complete transparency as to its process and assurances that the most appropriate items are on the Required Prior Authorization List.

The CQRC members believe that under any objective criteria, home oxygen therapy equipment, as well as sleep therapy equipment, should be on the Required Prior Authorization List. Historically, CMS, the Office of the Inspector General, and the GAO have raised concerns about bad actors in this area of health care. The relative size of reimbursement for oxygen-related equipment, as well as sleep equipment, argues in favor of inclusion in a prior authorization implementation process, not against it. The proportional cost savings associated with addressing items with large aggregate reimbursement figures outweigh any difficulties in implementation.

And, as more particularly described below, CMS's implementation of a prior authorization process for home respiratory therapy equipment generally, and home oxygen equipment in particular, should not be a difficult endeavor. For home oxygen therapy, the criteria used in determining medical necessity are objective in nature, allowing for a uniform, consistent process. Second, pre-existing, already-vetted Medicare processes can be leveraged and combined with standardized protocols presently in use by managed care plans to create an efficient, robust process, affording beneficiaries with timely access to equipment and also safeguarding the Medicare Trust Fund from paying for non-covered items and services. Implementing a streamlined process for such equipment will have a rapid and beneficial effect on the health and welfare of a significant number of beneficiaries.

Similarly, sleep-related equipment, which CMS appropriately includes on the Master List, should also be included on the Required Prior Authorization List as this equipment has also been subject to scrutiny in the past and also has objective criteria that can be provided in a prior authorization format to assure that beneficiaries in need of the equipment receive it, while easily identifying those that do not meet the necessary criteria.

Finally, the implementation of a prior authorization process for oxygen-related, as well as sleep-related, equipment will assist in alleviating the backlog of audit appeals. As described below, once the objective criteria necessary for the provision of such equipment is contained in a clear and complete form, the resulting uniformity and consistency in

determining medical necessity prior to providing items and services will have the beneficial effect of reducing the number, and effectively the types, of disputes submitted to the Medicare appeals process. This process of determining medical necessity at the outset will result in substantial financial savings for the Agency, as well as a program focused on the medical needs of the beneficiary. It will also improve the fiscal health of suppliers adversely affected by the backlog and afford the government an opportunity to employ its resources for other purposes.

The CQRC has been working for approximately two years to find a solution to the problems arising from the exponential increase in the audit volume. The vast majority of denials in audits do not relate to actual fraudulent activity, but rather involve auditors retroactively applying new rules or inconsistently in applying rules, ignoring documents submitted, and misinterpreting or overzealously searching for technical errors in Medicare requirements. The cost of adjudicating these claims is substantial and, while suppliers ultimately win and are paid, the delay in payment exceeds two years and, as reflected in recent Office of Medicare Hearings and Appeals (OMHA) data, may be closer to four or more years. Implementing prior authorization for home oxygen equipment and sleep equipment would eliminate most of the post-payment review audits and substantially reduce the sizable Administrative Law Judge backlog.

### **III. The prior authorization process should be tailored to each individual item subjected to it.**

While the Proposed Rule provides little specific detail about how prior authorization would be implemented, we assume that the lack of detail is due in part to the fact that, like managed care plans, Medicare will tailor the prior authorization process to the specific items being evaluated. A tailored prior authorization process would be consistent with the manner in which the Congress has tailored medical necessity criteria as well.<sup>4</sup> The statutory medical necessity criteria should be the basis for developing each prior authorization process.

For home oxygen therapy equipment, as well as for sleep therapy equipment, CMS should establish a process and timeline that follow those of managed care plans. In almost all cases, the plans use objective criteria. It is the objective nature of these criteria, among other things, that makes these types of equipment appropriate subjects of prior authorizations. Objective criteria are more easily communicated from providers and suppliers to the managed care plans through standardized forms and checklists and such information can be communicated in an expeditious manner. These plans often rely upon a web-based process, allowing for extremely efficient evaluation of each request and a timely decision.

Because the objective criteria used by managed care plans are similar to, if not in many cases the same as, those set forth by the Congress and CMS for use in the Medicare program, Medicare beneficiaries would likewise benefit from CMS' creation of a prior authorization process through which they will have appropriate and timely access to

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<sup>4</sup> 42 U.S.C. § 1395m(a).

medically necessary home oxygen therapy, as well as sleep therapy. Moreover, the inherent consistency and uniformity of Medicare guidelines, as opposed to varying policies and procedures contained in private managed care contracts, may lead ultimately to a Medicare prior authorization process with greater effectiveness as compared to those used by its commercial counterparts. We understand, at this time, that CMS does not have the ability to launch a web-based prior authorization system; however, we encourage the Agency to take the steps necessary now to develop such a system in the near future. Though a web portal would lead to even greater efficiency, the prior authorization process would retain its effectiveness if other means of communications are utilized: fax, email, phone and even mail.

Based upon our members' ongoing experience of being subject to prior authorizations by managed care plans, the CQRC has developed a set of recommendations that we strongly urge CMS to adopt for home oxygen therapy. Thus, the prior authorization process should:

- Include a simple, yet complete form that clearly sets forth the information that must be provided. Appendix A provides a model of a form for home oxygen therapy equipment, which is consistent with the existing objective criteria and medical documentation requirements.
- Assure that the prescribing physician submits medical information and is requesting the equipment and authorization.
- Allow for paper submissions, which could include facsimile or emailed attachments, using printed forms until a web-based submission process is established.
- Require the decisions made by the DME MACs to be based on completely objective criteria. CMS should provide specific, detailed guidance outlining the criteria and how they will be applied.
- Require that the decision be communicated to the physician and the supplier.
- Establish that a prior authorization number is a guarantee of payment in relation to medical necessity criteria, consistent with the Proposed Rule.
- Establish the responsibility of the beneficiary to pay for the item and services out of pocket, if a prior authorization is not obtained and Medicare does not cover the item and service, consistent with the Proposed Rule.
- Clearly state that the supplier would not be required to provide an item or services without first having a prior authorization number in hand, consistent with the Proposed Rule.

- Establish review and approval timelines that mirror those used by managed care plans for home oxygen therapy. There should be an expedited review process as well for equipment ordered immediately by the physician.

In terms of a timeline, we understand that CMS may have concerns that the contractors, unlike state Medicaid agencies, Medicare Advantage plans, and private plans, are not currently capable of adhering to a no more than 72-hour response timeframe. If this were the case, we would urge the Agency first to reconsider the contractors with which it is working and look to private sector entities who are more efficient. We also believe that prior authorization would bring needed clarity to the process that would reduce the burden on contractors and expedite review. For example, if physicians are providing the medical documentation, then they will have an added incentive to make sure the records are completed appropriately. Additionally, using best practices from other governmental and private payors, such as a clear template, will ensure that all of the information needed is provided in the first instance and will reduce the need to chase after additional documents. Also, unlike other types of DMEPOS items, the requirements for these therapies are objective and straightforward, as demonstrated by the current Certificate of Medical Necessity (CMN). Thus, the amount of time contractors will need to review claims should also diminish significantly.

There is no question that it is important for home respiratory therapy patients to receive their equipment in a timely manner. However, we do not believe that these types of equipment should be disqualified from a more efficient and effective process for targeting fraud merely because contractors are not capable of doing what the state Medicaid Agencies, Medicare Advantage plans, and the private sectors already do so well.

Therefore, we propose an alternative option upon which the Agency could rely if the contractors cannot meet the standard no more than 72-hour timeframe. Under this model, the Agency would require contractors to distinguish between prior authorization in the physician office and hospital discharge settings. In the case of the physician office setting, CMS could implement prior authorization for home respiratory therapy when physicians order the therapy during a patient's visit. The physician would initiate the request, the supplier could then provide the information that it is already permitted to provide on the CMN, and the contractor would have up to 10 days to approve the request. During that time, the supplier would not provide the equipment. An approval would constitute a finding of medical necessity and no audits of this determination would be permitted.

Consistent with the Proposed Rule, CMS could also implement an expedited prior authorization process for home respiratory therapy when a physician orders the therapy as a condition of release from the hospital. In that instance, the physician or appropriate hospital staff would initiate the request via phone or fax and the contractor would provide approval based upon the physician or hospital documentation within 24-48 hours. Suppliers should be incentivized to be as efficient in their review as possible. During that time, the supplier would not provide the equipment. Only suppliers that have posted a surety bond could provide the equipment and supplies in these instances. The Competitive Bidding Program requires a surety bond of at least \$50,000. Given the concerns about fraud, the CQRC

would support a requirement of a \$1 million surety bond for a company to participate in the expedited review process. Each company that wanted to participate in the expedited review process would have to obtain a surety bond at the company level; it would not need to be at the individual NPI level. An approval would constitute a finding of medical necessity and no audits of this determination would be permitted. By having the physician or hospital in the place of providing the justification, any concerns about supplier fraud should be eliminated. The security bond would stand as a high threshold for suppliers to meet and discourage fraudulent actors from trying to participate.

This bifurcated approach would allow contractors to take up to 10 days to process the less urgent requests, but still provide an expedited process to allow for prior authorization in the hospital discharge setting. As the Proposed Rule indicates there are times when an expedited review process is necessary. Thus, in addition to the rationale set forth in the Proposed Rule that allows for expedited review when “processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary’s ability to regain maximum function,”<sup>59</sup> we suggest including the need for a beneficiary to be discharged from a hospital in a timely manner.

We would welcome the opportunity to continue to share our experiences in working with prior authorizations in the managed care context to help develop the process CMS could use to implement it for the Medicare program.

#### **IV. The prior authorization process would be straightforward to implement.**

As referenced above, the prior authorization process in this instance would not be difficult to implement. We offer several reasons for this conclusion. First, physicians and suppliers already have experience with the process because some managed care, Medicare Advantage (MA), and Medicaid plans already require prior authorization.

Second, the current primary reasons for claim denials by CMS (and appeals by suppliers) relate to the lack of or inadequate physician documentation and DME MACs misinterpreting the requirements. Prior authorization would create a strong incentive for physicians to provide the appropriate documents. The process would also establish a clear, objective set of requirements that would make it less likely for DME MACs to make mistakes. It would also provide clarity to physicians and suppliers as to what they are required to submit.

Third, prior authorization works best as an electronic process that allows DME MAC reviewers to access the submissions quickly and in a consistent manner. Some Medicaid plans and Medicare Advantage plans already successfully rely upon web portals to collect the information, which would provide an available model that CMS could use for its process and web based system. We understand that the Agency may not be able to launch

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<sup>59</sup>9 *Fed. Reg.* at 30531.

prior authorization via the Internet immediately. However, prior authorization would create the appropriate incentives to help the Agency move closer to its goals of integrating health information technology into the Medicare program.

Prior authorization would not prevent DME MACs from using medical professionals to review claims. Instead, it should make their review more efficient by providing the necessary documentation up front. Having clear and consistent expectations for physicians as to what information is required would also streamline the process to reduce the amount of time that is required to review the requests.

Based upon our experience with managed care, MA, and Medicaid plans, we anticipate that the process would look like the following example.

1. The physician determines beneficiary needs oxygen and tells the patient.
2. The physician and supplier complete the form (see Appendix A for the objective data required on the form and the materials that would be required to be attached). In the physician office setting, suppliers would be permitted to complete those information sections of the prior authorization form that call for the same or similar information as the sections that suppliers are presently permitted to complete on a Certificate of Medical Necessity, CMS-484 – Oxygen (*i.e.*, Sections A and C of a CMN). In the hospital discharge setting, the physician or the appropriate hospital personnel completes the information.
3. In the physician office setting, the form may be sent by overnight mail, faxed, emailed, or submitted via an electronic portal (once available). While we appreciate that the Agency may want to allow for all options for submission, the Agency should seek to implement a web-based portal, which could be modeled off of existing managed care, Medicare Advantage, or Medicaid systems. In the case of the hospital discharge setting, there would be an expedited review. The physician or appropriate hospital staff emails or faxes the form and calls the DME MAC to discuss the prior authorization request. Since the physician or appropriate hospital personnel provide all of the information to determine medical necessity, the process should require less time to complete and concerns about fraud should be diminished.
4. The DME MAC reviews the form under the following timeline:

For a request from a physician's office, the DME MAC should make all reasonable efforts to review the materials expeditiously and provide a decision within 10 days. If additional information is needed, the DME MAC should contact the physician to provide it.

For a request for a hospital discharge, there should be an expedited review process. This could include providing material through a call and fax process for an immediate review. This discussion could occur between the physician (or the appropriate hospital staff) and the DME MAC. The built-in safeguard in this case is that the physician, rather than the supplier, is submitting the medical information. Thus, any concerns about the medical necessity of the item would be addressed live



with the person (or his or her representative) whose medical judgment is the basis for the determination. Additionally, for a supplier to participate in this expedited review process, CMS could require a surety bond from each supplier wishing to participate as well.

The expedited review process would work for oxygen and sleep therapy more easily than for other types of DMEPOS items because the Medicare requirements are very clear in terms of the medical criteria that must be provided. The current audit problem largely relates to physicians providing inadequate documentation. If physicians are required to provide the information to the DME MAC at the prior authorization stage, with clear guidelines, then they are more likely to provide the information required. Thus, the review process should not be as complicated as it might be for other types of DMEPOS items.

5. Once the DME MAC makes a determination, an approval via email or letter should be sent to the physician indicating that (1) the physician has prescribed oxygen for the beneficiaries and provided sufficient clinical data to make the determination; and (2) the prior authorization number. CMS can leverage its pre-existing, already-vetted communications protocols, such as EOBs, Medicare summary notices, in establishing this approval process and confirmation with the physician. In sharing the information contained in the approval with the physician, CMS could include a further safeguard that the appropriate information was in fact given to support the prior authorization, effectively providing CMS with a feedback mechanism, as well as protecting the Medicare Trust Fund paying for items and services not prescribed by the physician and, therefore, not covered by the program. In the case of the physician office setting request, a similar notification should also be provided to the supplier. If the prior authorization is denied, notice should be provided to both the physician and the supplier and include a notation that the supplier is not required to provide the equipment and services.

6. If the prior authorization request is granted, the DME MAC would provide a prior authorization number that the supplier would include with each claim submitted for the particular patient. In the physician office setting, the supplier could obtain that prior authorization number directly from the DME MAC or from the physician. In the hospital discharge setting, the supplier would receive it directly from the physician or the hospital personnel who obtained the approval.

7. The DME MAC would review each claim and if a valid prior authorization number is provided on the claim, then the claim would not be subject to further medical necessity review.

This process would differ in important ways from the current audit process, but not create a significant burden on physicians or hospitals. For example, in the hospital discharge setting, the physician prescribes the oxygen. Usually the discharge planner works with the family to determine the supplier from which the patient will receive his/her oxygen equipment. Today, the supplier is called, meets with the patient, and arranges for the delivery. Our recommendations would add a step after the physician prescribes the equipment that

requires the physician or appropriate hospital personnel to submit the documentation through the expedited review process. The patient would still select a supplier from a list provided by the hospital, but in our recommendations only suppliers that have a surety bond would be permitted to be on the list that is shared. Once the patient selects a supplier, the physician or hospital would provide the prior authorization number to the supplier. The supplier would then provide the equipment and include the prior authorization number on the claims.

We anticipate that the time DME MACs need to conduct medical necessity reviews would decrease substantially. Once physicians and hospitals have an interest in ensuring that the appropriate documents are provided to contractors, there will be significantly less time spent chasing documents. Also, physicians and hospitals will understand better what documentation is necessary which should streamline the process and further shorten the time needed to review requests.

**V. The result of a prior authorization process should include the elimination of medical necessity audits.**

The CQRC strongly supports CMS' stated position in the Proposed Rule and the June 17 Open Door Forum, that an affirmative decision on a prior authorization request would eliminate subsequent audits related to medical necessity determinations.<sup>6</sup> As the Agency notes in the Proposed Rule, prior authorizations would not change documentation requirements, but would clarify such requirements in an objective manner. Thus, physicians would share in the responsibility for ensuring that their patients receive timely access to medically necessary items and would have a better understanding of the information CMS needs to approve the request. Prior authorization should create a clear set of requirements and eliminate confusion or any need for interpretation of current objective criteria for the provision of oxygen therapy equipment. This policy would also align Medicare with managed care plans.

Additionally, CMS should clarify that the prior authorization approval meets the written order prior to dispensing rule, since in essence, submission of the prior authorization is just that – providing the written order and request, along with additional information, prior to the supplier dispensing the equipment.

**VI. Although CMS should implement prior authorization nationwide, the CQRC would also support a phased-in approach based upon those areas of the country with the highest error rates.**

The CQRC strongly urges CMS to implement a national prior authorization process for home oxygen therapy equipment, as well as for home sleep therapy equipment. This approach would align Medicare with the best practices of state Medicaid agencies, Medicare Advantage plans, and private plans. However, we understand that concerns may exist about applying prior authorization to these types of equipment or services due to the volume of

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<sup>6</sup>79 *Fed. Reg.* at 30520.

services and the ability of contractors to meet the standard timeframes of other reviewers. The benefit of clarity to both CMS and suppliers that prior authorization affords outweighs any potential concern. However, if it would help allay concerns, the CQRC would support a phase-in implementation as an alternative to complete exclusion. For example, a multi-year phase in could begin by implementing prior authorization in competitive bidding areas. Another option would be to phase-in the program by DME MAC jurisdictions. In that instance, we would recommend beginning in Region C because the disproportionate number of denials for medical necessity that our members have experienced in that region. While a nationwide approach is preferable, CMS should not allow concerns to exclude home oxygen equipment or home sleep equipment from the prior authorization program.

**VII. CMS should set forth the appropriate metrics for evaluating the success of prior authorization.**

Finally, CMS should ensure transparency by identifying the criteria it will use to evaluate the success of the program. While it might be tempting to use changes in utilization patterns, this criterion would not accurately measure the success of the program. Put simply, the enormous problem with the current audit system has created an entirely false picture of the actual utilization. For example, if Administrative Law Judges are reversing more than 80 percent of the claim denials (as our experience shows) yet utilization is determined using the initial denial rates, the current utilization levels are significantly distorted.

We believe a more appropriate and more accurate set of criteria would include measuring preventable hospital readmissions and delays in hospital discharges. These factors are consistent with the Agency's National Quality Strategy. They are also consistent with the quality factors upon which the Medicare Payment Advisory Commission (MedPAC) recommended CMS rely in its June 2014 *Report to the Congress*.<sup>7</sup>

Most importantly, these factors focus on patient outcomes and access to medically necessary items. Home respiratory therapies provide value to patients because these therapies allow patients to remain in their homes rather than having to live in an institutional setting or experiencing repeated hospital visits. Thus, examining preventable hospital readmissions as related to the provision of home respiratory therapies would appropriately set the focus on patient outcomes, as well as demonstrate the savings to the Medicare program. Secondly, one concern regarding prior authorization could be related to maintaining patient access. Measuring delayed hospital discharges for patients requiring home respiratory therapies would hold physicians and suppliers, as well as CMS contractors, accountable for ensuring the timeliness of the submission, review, and issuance of prior authorization requests. To ensure transparency, CMS should set forth the criteria it plans on using in the final rule and make its evaluations available to the public.

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<sup>7</sup>Medicare Payment Advisory Commission (MedPAC), *Report to the Congress*, "Measuring quality of care in Medicare" 39-56 (June 2014).

**VIII. Conclusion.**

The CQRC appreciates the opportunity to provide comments to CMS on the Proposed Rule. As noted, we strongly urge the Agency to implement prior authorization for home oxygen equipment, as well as home sleep equipment. Both types of equipment meet the requirements CMS set forth in the Proposed Rule for being on the Master List. Managed care already requires providers and suppliers to obtain prior authorization for these types of equipment. We welcome the opportunity to work with your team to ensure that the process for implementing prior authorization for these types of equipment will work for beneficiaries, physicians, and suppliers. Please do not hesitate to contact me at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,



Kathy Lester  
Executive Director  
Council for Quality Respiratory Care

cc: Deborah Taylor, Director Office of Financial Management, Chief Financial Officer  
Melanie Combs-Dyer, Acting Director, Provider Compliance Group  
Jill Nicolaisen, Director, Division of Medical Review and Education  
Daniel Schwartz, Provider Compliance Group  
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**Appendix A: Suggested Electronic Clinical Template  
For Prior Authorization of Initiation of Home Oxygen Therapy**

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A. Beneficiary Information

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- A1. Beneficiary Name and Address
  - A2. Beneficiary Medicare Number
  - A3. Beneficiary Date of Birth
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B. Physician Information

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- B1. Physician Name, Address, Phone Number
  - B2. Credentials (pull down menu *e.g.*, MD, PA, NP)
  - B3. NPI
  - B4. Physician Attestation (Check Box)
  - B5. Physician Digital Signature and Date
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C. Service Details

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- C1. Date of Prescribing the Therapy (calendar fill in)
  - C2. Patient Diagnosis (code)
  - C3. Order for Home Oxygen Therapy (pull down menu)
  - C4. Liter Flow Prescribed (pull down menu)
  - C5. Frequency (pull down menu)
  - C6. Duration (option to insert number of months or 99 for lifetime)
  - C7. Description of Modality (pull down menu)<sup>8</sup>
  - C8. Selection of Cannula or Mask (pull down menu)
  - C9. Attach Copy of Physician Dispensing Order
  - C10. Attach Copy of Initial Evaluation
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D. Notes of Face-to-Face Visit

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- D1. Date of Visit
  - D2. Describe the Beneficiary's Condition (pull down memo with optional narrative)
  - D3. Describe the Beneficiary's Need for Home Oxygen Therapy (pull down memo with optional narrative)
  - D4. Describe How the Beneficiary will Benefit from the Use of Home Oxygen Therapy (pull down memo with optional narrative)
  - D5. Attach Copy of Face-to-Face Visit Notes
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E. Qualifying Test

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- E1. Test Condition (pull down menu *e.g.*, at rest, during exercise, during sleep)
  - E2. Oxygen Saturation Test Date (calendar fill in)
  - E3. Oxygen Saturation (insert value) (pull down menu for type of test)<sup>9</sup>
  - E4. Attach copy of Test Documentation
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F. Supplier Information

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- E1. Supplier Name, Address, and Phone Number

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<sup>8</sup>Modality Options would include: Liquid, Concentrator, Portable.

<sup>9</sup>Test options would include: ABG, Overnight Oximetry Test, Resting Test, 3-Step Testing (Rest without O2, Exercise without O2, Exercise with O2)

### Potential Prompts in Narrative Description

The narrative description could be a series of boxes with the following questions. It might look something like this:

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#### Physician Description of Patient's Respiratory / Pulmonary Exam

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What is the patient's condition (*e.g.*, lung disease or hypoxia related symptoms)?

Physician would insert narrative to answer specific question

What is the prognosis of the patient's condition?

Physician would insert narrative to answer specific question

What is the patient's need for this therapy (*e.g.*, state if oxygen is needed on a continual basis or could current therapy be replaced with an alternative therapy)?

Physician would insert narrative to answer specific question

How will the patient benefit from the continued use of this therapy?

Physician would insert narrative to answer specific question

What is the likelihood of the patient needing emergency room and/or hospital care if therapy is not provided?

Physician would insert narrative to answer specific question