



## **NxStageUsers Home Dialyzer Action Plan for Bundling**

*Create cheat sheet to lead people through the open comment period. Agree with what we like and ask more than what we can get.*

*All comments to CMS should be blind copied to us. We need to match responders to Congressional districts for follow up for bundle and afterwards for future action. It's a good idea we do this regardless with NxStage dialyzer base. We should have database expanded for Congressional District field and have CS modify for each. All we need is zip+four.*

### **Intro to End Stage Renal Disease Prospective Payment System**

Last year, Congress passed the Medicare Improvements and Patients and Providers Act (MIPPA). This legislation requires the Centers for Medicare and Medicaid Services (CMS) to develop a new payment plan for the bundling of dialysis services. It is the most far reaching change in the way Medicare pays for dialysis since 1983. For the last 26 years, dialysis was paid for with what was called the "composite rate". This included the dialysis treatment, certain injectable med and some labs. The new "bundling system is to be phased in over four years beginning in 2011. Bundling will include the dialysis treatment, all meds considered for renal failures, including epo and orals, and all labs. This represents a significant change from the "composite rate".

Some of the dialysis community's concerns prior to the release of the proposed rules were decided upon favorably by CMS. Those were namely a unit of payment on a per treatment basis. There was much discussion about it being paid out on a per week or per month allocation based upon 13 treatments per week. Also, there was talk about discontinuing the practice of allowing extra treatments justified by medical necessity. Both would have been problematic for home dialyzers. Fortunately, CMS has decided not to change either. We should praise CMS for making the right choice.

However, there are still some issues which remain that would benefit home dialysis. One major one is the cost of training. In the past a dialysis unit received \$20 for each training session, and that was outside of the "composite rate". That figure was already a mere drop in the bucket of what training costs. It's estimated that the cost of a registered nurse alone is as high as \$200 per training period. But CMS is proposing that training be part of the total bundled rate, which means the unit is to absorb the cost of training. It is feared that this would be a disincentive for some units to continue its home program. If this occurs, many current home dialyzers might lose their modality of choice.

Also, all meds and many labs now to be included, there is concern as to whether dialyzors will be able to afford them. Prior, many meds and labs were paid for 100% by Medicare, while others were covered by Medicare Part D, while labs were also paid for outside the old composite rate. This is about to change. Because Medicare only pays 80% of customary costs, the remaining 20% must be paid for by a Medigap policy, secondary insurance, or the dialyzor. As you know, there are many very expensive meds and labs a dialyzor takes. The concern is whether dialyzors will be able to receive the meds necessary to remain healthy. Also because some meds are quite expensive such as binders (Renagel, Phoslo), activated vitamin-D (Zemplar, Hectoral) and cinacalcet (Sensipar), there's a concern less expensive and effective meds may be prescribed to save the clinic money.

In addition, there are case-mix adjusters for things such as race/ethnicity/ gender/co-morbidities/ geographic area, etc. They basically increase or decrease the amount reimbursed for individuals. This can affect co-pays as well regarding the 10% Medicare won't pay for.

Other issues include the Quality Incentive Program CMS is to develop. This is part of a separate rule which will become effective in 2012, but they are looking for comments. Currently CMS is considering adequacy and two anemia management standards, but what about hospitalizations, in which home dialyzors are scoring better? What about other indicators like phosphorus, bone mineral metabolism, iron management, vascular access, hospitalizations, fluid overload, cardiovascular and overall survivability? Surely we can make the point here that home dialysis can provide a more optimal treatment rather than just adequate (whatever that is). This is an area we can stress how much better home dialysis is as a modality and how it has affected our lives.

So what can we do? One very important thing to do is to write to CMS about your concerns. This is done during what is called the "open comment period". In addition to writing to CMS, you can also talk to as many other dialyzors, family and friends as possible about the need to write. Most people don't get involved in the nitty-gritty of government policy. But we're talking about something which will affect our lives for years to come, and can be the difference in remaining as healthy as we can be.

In addition, you can write to your Federal Representatives and ask them to write to CMS. Developing a relationship with them and their staff is positive regardless of this current issue. We will undoubtedly need to continue to have legislation passed to support other issues like more frequent dialysis without the need to justify extra treatments because of medical necessity. The process never ends.

### **Comment on the End Stage Renal Disease Prospective Payment System**

CMS has set up a 60 day window for interested parties to make comments regarding the ESRD PPS. The deadline for submitting comments is **November 16<sup>th</sup> at 5:00 pm.**

Comments can be sent by several methods, or can be hand delivered. The preferred methods are by email or regular mail. In writing your comments to CMS, please do so from a dialyzer perspective. There's no need to get too technical or even appearing to know the ins and outs of the proposed rules. Remember you're the patient and not the professional that lives and breathes policy. Therefore, keep it simple. There will be plenty of others who'll wax legalese. Although CMS may be looking for specifics, including comments on actual dollar figures, don't write about it if you're not knowledgeable or comfortable. It is important CMS hears from dialyzers, even if the comments are used as background information. **In commenting, please refer to file code CMS-1418-P. Please include your address and zip+four and send a blind copy to [Bundling@NxStageUse rs.com](mailto:Bundling@NxStageUse rs.com).**

**1. Electronically**

You may submit electronic comments on this regulation to <http://www.regulations.gov>.

**You must include File Code CMS-1418-P in the subject line. Or electronically by the form located at <http://www.regulations.gov/search/Regs/home.html#submitComment?R=0900006480a30c15>. We prefer you send an email rather than using the form.**

**2. By regular mail**

You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services,  
Attention: CMS-1418-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

**3. By express or overnight mail**

You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services,  
Attention: CMS-1418-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

**4. By hand or courier**

If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

For delivery in Washington, DC--

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the

Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--  
Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500  
Security Boulevard, Baltimore, MD 21244-1850.  
CMS-1418-P4

If you intend to deliver your comments to the Baltimore address, please call telephone number  
(410) 786-9994 in advance to schedule your arrival with one of our staff members.  
Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be  
delayed and received after the comment period.

**FOR FURTHER INFORMATION CONTACT:**

William Cymer, (410) 786-4533.

Lynn Riley, (410) 786-1286, (ESRD Quality Incentive Program.)

**Now what to write**

- Write a little about yourself.
- How long have you been on dialysis?
- How long at home?
- Differences between the two.
- What has home dialysis has meant to you?
- Write if hospitalizations have decreased.
- Are you using fewer meds: binders, epo, and blood pressure?
- What do you like about the proposal?
- Per treatment unit of payment.
- Extra treatments due to medical justification.
- What changes would you like to see? And why? You may want to see home programs remain strong because you feel your wellbeing depends on it. Without reimbursement for training, some home programs may be less willing to continue with new dialyzors.

Also, labs and meds, including those which are normally prescribed for dialyzors. will now be part of the bundle, and subject to Medicare payments of 80%. Previously, they were outside of the composite rate and Medicare paid 100% of the permissible labs and meds. There is concern that many dialyzors won't have insurance to pay for the 20% gap.

- Training -

- How many weeks did you require?
- Describe what you learned.
- How intense was the training?
- How much time did your trainer spend with you?
- Could you have gone home without it?

o There is a 47.3 % adjustor for the first four months if a dialyzer starts immediately on Medicare. Many believe this is illogical, especially considering that home training costs are included in the bundle and not paid separately as it is currently. There is great concern that without centers getting paid for training, there will be a disincentive to continuing a home program. Almost 9 in 10 home hemodialyzers first start dialysis in-center. Therefore, the adjustor wouldn't apply to their training, but rather to the in-center dialysis clinic they first attended. We believe the adjustor, or a portion, should be available for training, or that training should remain outside the bundle.

- What were your 1<sup>st</sup> four months on dialysis like? Did you receive any special considerations, i.e., education?
- Were your first 4 months in-center or home?
- Did you start with Medicare from the onset of beginning dialysis?
- How would you compare the 1<sup>st</sup> four months of in-center vs. home regarding the support you received.
- Meds and labs outside of bundle or not subject to 80/20% rule.
- Will you have difficulty paying the 20% co-payment?
- Do you have a Medigap or a secondary insurance policy?

### **Into the future**

The bundling proposal is not the last issue home dialyzers will face – it's just the beginning. Getting better payment for treatments and beneficial government policies is a process. After bundling we will have to work on such things as payment for more frequent dialysis without the need for the tedious requirement of justification because of medical necessity. By being able to decide upon our modality of choice, there should be no barriers to having them. This may very well be a major hurdle since we're no longer talking about "budget neutrality", or using the same amount of funds available today.

Because of the need to keep on trucking, we want to develop a core of people who are willing to get more involved. This could be as little as getting involved in writing or petitioning your representatives to actually setting up visits to your center or going to meet with them. This is one reason why we want you to send us your zip+four. We'll then be able to keep track of where we have an advocate and where we need to find one. You can also send this information in separately to: [Bundling@NxStageUsers.com](mailto:Bundling@NxStageUsers.com)