CMS-4004-FC-1 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Mrs. Sharon Helstein-Korncavage** **Date & Time:** **12/29/2004**

Organization : **Law Office**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

I deal with Liens and seem to not know if there is a Lien of a client when we do a settlement. I recently sent paper work to medicare on a client did every thing told to due and now 90 days plus have heard nothing and a settlement will be coming in 2005.

CMS-4004-FC-3 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Dr. Clarice Powers** **Date & Time:** **01/14/2005**

Organization : **Home Healthcare Connection, Inc.**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

NOTICE OF MEDICARE PROVIDER NON-COVERAGE COMMENTS
Clarice J. Powers, RN, PhD
Home Healthcare Connection, Inc.
4747 S. Emporia
Wichita, KS
(316) 267-4663

The new ?Notice of Medicare Provider Non-Coverage? requirement published in the Federal Register November 26, 2004, is an outrageous, egregious misuse of governmental (CMS) authority. The new notices are unnecessary and will be confusing to clients. It once again imposes an unfunded mandate on home health providers who have already been adversely effected by the Balanced Budget Act of 1997. Hand-delivering this new notice is an absolutely unnecessary use of qualified health care staff at an unreasonable expense.

The projected cost of $2.50 per notice is outrageously underestimated. A more accurate cost is estimated at more than ten times that amount and is realistically between $30-$50, depending on geographical location.

According to ?home health line, December 17, 2004, Volume XXIX, No, 47, ??CMS will probably take any comments into consideration, but will most likely not alter or amend the regulation,? the article states. How arrogant! Our government should serve the people, not bleed them (of time, money, and other limited resources).

The current use of the Advance Beneficiary Notice (ABN), previously imposed, meets any notifications needed for beneficiaries. Adding a new notice, without reducing an existing one, contradicts the government?s Paper Reduction Act.

We object to this proposed regulation and recommend its immediate removal from the Federal Register.

CMS-4004-FC-4 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Pam Tidwell** **Date & Time:** **01/17/2005**

Organization : **CarePartners-Visiting Health Professionals**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

CMS-4004-FC Discharge notification

This proposed regulation creates enormous operation hardships in its current state. There are practical and time problems with the proposed process.
Today the required discharge date is date of last visit. To meet the 48 hour required notification staff will need to give notice on second to last visit, to avoid visits with no skilled service. This second to last visit could be 2 weeks prior to last visit. In real world much can happen in two weeks.
Recommend you drop the 48 hour rule; drop the time component and allow staff to deliver on last visit.

This required notification on ALL patients impact numerous Recommend we put undated appeal process in admission packet. This gives patient upfront information about process.
Recommend we eliminate dated notification on 2 patient populations.

Hospitalized patients: Most hospitalizations are unexpected. We keep patient in our active home health status for several days while in the hospital, to avoid total home health admission process (4 hours). Should patient return in few days, we can recertify and proceed with care plan. If patient stay several days and we need to discharge, this notification is hardship.

Unanticipated LUPAs: It is practically impossible to predict a LUPA patient on admission. I recommend you eliminate the notice for unanticipated or all LUPAs.

CMS-4004-FC-5 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Mrs. teresa ledgerwood** **Date & Time:** **01/17/2005**

Organization : **Mrs. teresa ledgerwood**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

adding an additional form for home health providers does nothing to better patient care - but only adds more paperwork burden to the providers. HHC providers already have the ABN - why add an additional form that brings no value to the care that the patient receives. Who thinks this paperwork up? They have not been in the homecare arena for sometime.... Thanks for your consideration.

CMS-4004-FC-6 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Pam Tidwell** **Date & Time:** **01/18/2005**

Organization : **Visiting Health Professionals**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

The proposed federal regulation requires patient to get a physician statement of continued need in order to appeal. This is not referenced in the proposed form to patient. The patient is instructed to call the Quality agency. This needs clarification.

CMS-4004-FC-7 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Mrs. Phyllis Fredland** **Date & Time:** **01/20/2005**

Organization : **Health Personnel Inc.**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

COMMENTS ON STATUARY CHANGES TO THE APPEALS PROCESS

There are many glaring problems that we see with delivering a notice of planned discharge 2 days prior to the discharge. They are as follows:

1. If the patient appeals the discharge and has the necessary physician certification that it would harm the patient?s health, we are asking a home health agency to give care without doctor?s orders, which is illegal and also jeopardizes licenses of staff. No nurse, PT, OT or ST can practice skilled procedures without a doctor?s order under any of the practice acts here in Pennsylvania. Also if the agency is wrong according to the QIO, the agency will then have to do a new start of care chart which takes approximately 4 hrs of a nurse?s time to complete. This cost was not factored in when the cost of $20/ patient was projected. Since according to the Medicare regulations a patient is suppose to be stable for 3 weeks before discharge, I would suggest the 2 day window be made into a 7 day window at the very least.
2. Since the vast majority of patients can not afford to pay for the services you will be leaving agencies at risk of financial failure because of bad debts. I would suggest that the patient be required to put money into an escrow account to cover the cost before they are allowed to appeal.
3. By allowing the patient only until 12 noon of the day they are notified to appeal, you are making it impossible for a caretaker to intervene and file an appeal. Many of our patients are too confused to understand their appeal rights and the caretakers often are not constantly there. We suggest that they have a 2 day window of opportunity to appeal
4. If the QIO decision is appealed are the home health agencies required to continue the care without orders. And if so if the patient cannot pay the bill who will?
5. I would suggest that with the discharge notice, the patient be given the information on the standards they have to meet to qualify for care.
6. In home health care, patients may be transferred to an in patient facility and expected to return to service but instead get discharged because they go to SNF, rehab facility or die. We would not have given these patients a discharge notice. We are assuming discharge notice is not required, but this makes an inconsistency in paperwork.
7. Since home health agencies, are notified by the QIO that an appeal has been filed and must give the QIO the reason the patient does not qualify by the close of business that day, are we now requiring agencies to keep the office staffed on weekends and holidays? This will increase operating cost significantly.
8. Also our agency office closes at 4:30 PM, but the QIO office does not close until 5PM and there is no requirement in the regulations that the QIO notify the agency by a certain time. I would suggest that the QIO be required to notify the agency by 1 PM of the day they were notified by the patient of the expedited appeal.
9. To release the information, because of HIPPA and confidentiality, another form will have to be signed by the patient. But when?

CMS-4004-FC-8 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Ms. Diana Smith** **Date & Time:** **01/24/2005**

Organization : **Ms. Diana Smith**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4004-FC-8-Attach-1.DOC

Attach # 8
Diana Smith, RN
8 Hill Court Hercules, CA 94547

January 23, 2005

Centers for Medicare & Medicaid Services
Attention: CMS—4004—FC
P.O. Box 8016
Baltimore, MD 21244-8016

In response to file Code CMS-4004-FC

Based on my experience as an Appeals Specialist for a QIO, I wanted to make some Comments on the proposed regulations listed in the Federal Register. I am concerned that the proposals do not take into consideration the current appeals processes that are in place and that they do not assist the beneficiaries in the way that they are perhaps intended to assist them. Below are my personal opinions, not reflecting the views of the QIO for which I am employed, on the Federal Register.

Issue Identifier: Expedited Determinations

Issue: A beneficiary may appeal termination of services from an HHA or CORF only if a physician certifies that the termination of services is likely to place the beneficiary's health at significant risk.

Comments:
The statement that an HHA intends to terminate services and the physician certifies that termination of services is likely to place the beneficiary's health at significant risk as the only criteria for a beneficiary to be able to appeal the decision to terminate services for Home Health Agency (HHA) or Comprehensive Outpatient Rehabilitation Facility (CORF) services does not correspond with the ability to appeal from an inpatient provider, such as a Skilled Nursing Facility (SNF) or hospice. This might be a source of confusion for caregivers as well as beneficiaries. Additionally, the Medicare Advantage (MA) appeal process, which this appeal process was modeled after, does not create this distinction between in-patient and outpatient provider termination of service appeals.

How does CMS define "certification" and "significant risk" as is used in this provision?

Does this mean that the beneficiary cannot appeal unless he/she has a note from their doctor, or is the physician the only one that can appeal this termination of services? Can the beneficiary appeal and then try to get their own physician to certify the significant health risk? This "significant health risk"

terminology (and provision) does not exist in any of the other appeals processes, and puts an unworkable constraint on filing an appeal for termination of services from a non-residential provider (i.e., HHA or CORF), especially within the time frames that are mandated for the beneficiary to file their appeal.

I currently work for a QIO, in the appeals department and noticed that, to date, under Grijalva, we have not had any appeals from a CORF, and the appeals that we have had from HHA, most of them were due to lack of authorization for additional days that were authorized as soon as the appeal was filed. Of the appeals that went through to completion, none were required to have the physician "certify a significant health risk" to the beneficiary" for the beneficiary/representative to appeal.

Recommendations: If you were to remove the language differentiating between in-patient (SNF) and out-patient (HHA and CORF) provider termination of service appeals and remove the language requiring a physician to certify that the termination of services is likely to place the beneficiary's health at significant risk, then the language and appeal process would match the appeal process currently in place, effective and practicable in the Medicare Advantage appeals process.

Issue Identifier: Expedited QIC Reconsiderations

Issue #1: Currently, the beneficiary expresses their dissatisfaction with the outcome when they are notified of the results of the outcome of the review. The QIO was able to immediately begin the reconsideration process and, in some cases, send the record to another physician reviewer the same day for a second review. The proposed change to having a QIC perform the reconsideration appears to place additional burden on the beneficiary (or their representative) if the beneficiary is dissatisfied with the outcome of the initial appeal.

Comments:

It appears that the beneficiary (or representative) will be required to make an additional telephone call to the QIC to request the reconsideration and repeat all the that they had given to the QIO when they requested their original appeal and then add the reason they are requesting the reconsideration. Many beneficiaries would find this an unworkable burden to have to make an additional phone call to provide that information. Additionally, there are instances when the Appeals Specialist has disagreed with the outcome of the initial determination and sent the record for a reconsideration for the beneficiary's benefit. Under the new format, it does not appear that the Appeals Specialists would be able to solicit a reconsideration review unless the beneficiary requested one of the QIC.

Recommendation: Since apparently the Congress intends that there be a separate entity (not just a separate physician reviewer) perform the reconsideration review, having the QIO forward the call and the file to the QIC is a possible solution. This would require more time spent in faxing records to the QIC, more opportunities for breach of confidentiality (as records are being sent out). The QIC would then contact the beneficiary (or representative) to solicit their views regarding the case and why they want a reconsideration. It would remove the excessive burden from the beneficiary, but it would place it on the QIO, which would cost money in terms of time and resources used to forward the calls and

information. Another solution would be to continue the reconsideration as it now stands, having the QIO perform the reconsideration with a different physician reviewer performing the review. It would cost less, be less burdensome on all parties. The last is to force the beneficiary to make an additional phone call if they wish to make a reconsideration. Since this requires additional work on the part of the beneficiary, there is a likelihood that the number of requests for reconsiderations would decrease. This would cost less and be less burdensome to the QIO and QIC, but it would at the personal cost of those who do not undertake requesting a reconsideration because of having to make additional phone calls to make that request and lose the opportunity to have the adverse determination overturned.

Issue #2: The beneficiary (or representative) must be available to talk to the QIC (or QIO in other portions of the proposed regulations) about his or her case.

Comments:

The QIO's have occasionally had problems with availability of the beneficiary's representative, and having the beneficiary (representative) required to be available to talk about the case as part of the regulation would be of some help. As it stands, if the QIO is unable to contact the beneficiary (or usually, beneficiary's representative) with the outcome of an appeal, then the liability cannot begin until the QIO can give them the adverse outcome of an immediate (acute provider) appeal. While it would not be fair to suggest that it was a deliberate act on the part of these beneficiary's representatives who are well aware of the regulations, there are some "repeat customers" for whom this is a pattern of behavior. In the majority of cases, when the representative is difficult to reach, it is because they are actually engaged in taking care of business related to the health care of the beneficiary. There needs to be acknowledgement that while it is expected that the representative needs to be available to discuss the case, CMS/QIO/QIC also recognizes that the representative has other business that they may need to attend to as well.

Recommendations:
The current appeals language does not contain any language that the beneficiary (representative) "must be available to talk about his or her case" and it isn't clear from the proposed regulation if this statement will appear on the notices or just in the regulations. Having the statement on the notice, in the section on how to request an appeal, would be the best location for this language. At best, this statement will only be a suggestion, because there is no real way to enforce "availability" of the representative. The current process allows that the QIO can attempt to solicit the views of the beneficiary (representative) and there are processes for mailing the notice of an adverse determination by certified mail, in the event that the beneficiary (representative) is not available. It would be welcome to have the new language applied to all of the current appeals processes and added to all of the notices that are currently in use.

Issue #3: The beneficiary may not be billed during the appeals process.

Comments: Beneficiaries, in some facilities, have been coerced or harassed into leaving a facility, even after filing an appeal, before they were medically ready to leave. There have been instances where

hospital personnel have told beneficiaries that they will be billed for their entire stay if they lose their appeal, that the hospital has never lost an appeal, that the QIO has declined to accept their appeal (when the QIO had accepted the case), that the QIO had found in favor of the hospital (when the QIO hadn't even received records to begin a review yet), the nurse called the police to escort the beneficiary off hospital property, etc. The beneficiary is clearly at a disadvantage when filing an appeal. Nurses have stopped providing medications and treatments "because we have a discharge order" and there have been other incidents of similar situations arising.

The proposed language states that the provider may not be billed, but it does not say that the patient will not be liable. After filing an appeal, the beneficiary has no control over the speed at which the provider makes the medical records available to the QIO. The provider has no financial incentive to provide the records so that the QIO can issue its determination prior to the date that the beneficiary becomes liable for payment. The QIO's incentive for issuing its determination in a timely manner is in keeping their contract with CMS, but that does not necessarily mean issuing it before the patient becomes financial liable for a portion of their stay. The other immediate appeals processes cover the beneficiary's liability during the initial appeal process until the beneficiary is notified of the determination. This should also be the same here.

Recommendations:
There needs to be clearly defined penalties for harassment of a beneficiary who files an appeal. Beneficiaries are vulnerable to the actions and misinformation given to them from provider staff. Beneficiaries need to feel that they won't be retaliated against, if they should choose to appeal their discharge or termination of services.

The financial liability should not begin until the beneficiary (representative) is notified of the determination of the initial review.

Issue Identifier: Analysis and Response to Public Comments

Issue #1: Under section 405.1200(d) explanation, you state that the effect of the changes is that the beneficiary could face financial liability if the QIO rules that the discharge is appropriate.

Comments: This is unfair to the beneficiary and penalizes the beneficiary for filing an appeal. The appeals process for the MA expedited appeals process for non-acute appeals began this way and had been amended to reflect no liability for the beneficiary while the initial appeal process was in process. Whether the provider delays providing the records or if the QIO delays providing a decision, it is not under the beneficiary's control, and the beneficiary should not be held responsible. The beneficiary may request a reconsideration at their own financial risk (as they do in the other appeal processes), but it would not be fair that the initial appeal would be at financial risk, as the provider has no financial incentive to get the records to the QIO in time to get a result by the date the beneficiary becomes financially liable for any part of their stay. If the provider, deliberately or not, delays producing the records, then the beneficiary will end up being billed before they are notified of the outcome of their

appeal. This can not be what the spirit of the law (regulation) was when the appeals process was set up.

Recommendation: The beneficiary could become liable on the date stated on the notice, or on noon the day specified by the QIO (in the case of delay in making the determination), as it is with the other review processes.

Issue #2: §405.1202(e) states that the deadline for the QIO's determination is 72 hours from the receipt of the request for a review and that the provider may be held financially liable for continued services resulting from a delay in providing necessary information.

Comments: This could have the QIO out of timeline (i.e., no determination within 72 hours from receipt of the request for a review) because the QIO had to delay a decision due to the provider not supplying the necessary information. The QIO's had this problem with the acute appeal process, and it was remedied by changing the deadline to 24 hours after receipt of the records. This allows time for the review by the QIO without penalizing the QIO for events outside their control.

Recommendation: The proposed regulation would complement the regulations in the other appeals processes by changing the time that a determination is due to 24 hours after the QIO receives the medical records from the provider.

Issue Identifier: Expedited Determination Procedures

Issue #1: In all of the language for requesting appeals, the language exists that the beneficiary must "submit a request for an appeal to the QIO, in writing or by telephone, by no later than noon…" and the QIO has, on occasion, received letters sent by regular mail to request an appeal.

Comments: The language "in writing or by telephone" can be confusing in the context of requesting an immediate or concurrent appeal. For example: The beneficiary/representative mails the letter (via first class mail) before noon the day after they received the notice of non-coverage (or termination of services), thinking that they were making a timely request. It arrives, via regular mail delivery several days later. If the QIO accepts this as a timely request, the beneficiary gets an unfair extension of their stay at the hospital without incurring any liability for the extra days during the mail "delay." If the QIO does not accept this as a timely request, the beneficiary is deprived of their appeal rights, as the beneficiary feels that he or she is following the directions as written.

Recommendation: The language should be changed to reflect that the review should be received by noon, or be requested by facsimile or telephone, or something to that effect, so that neither the provider nor the beneficiary are put at an undue disadvantage or burden.

Issue #2: The proposed regulation lists 15 minutes as the average time that an initial call to file an appeal would take.

Comments: In our office, the average length of time that an initial call, to file an appeal, is 30 minutes.

Recommendation: I am not sure what process is used to determine your time estimates as you listed them, and a description of how you determined these estimates would be helpful. The time estimates you listed have the appearance of being unrealistically short of actual time involved. Many of our discussions with beneficiaries, case managers and beneficiary representatives lead to the following: average time for initial call for appeal (including a short, initial solicitation of views) is 30 minutes, average time for preparing initial notice is 5 minutes, average time to give notice (including making sure patient understands appeal rights) is 15 minutes. This will probably impact your final calculations as to the number of hours per year and the associated cost involved in the new appeals process.

Issue Identifier: §405.1202

Issue: Paragraph (a)(1) that services furnished by a non-residential provider can be appealed only if a physician certifies that failure to continue may place the beneficiary's health at significant risk:

Comments: (see statements listed above—copied here)

The statement that an out-patient provider intends to terminate services and the physician certifies that termination of services is likely to place the beneficiary's health at significant risk as the only criteria for a beneficiary to be able to appeal the decision to terminate services for Home Health Agency (HHA) or Comprehensive Outpatient Rehabilitation Facility (CORF) services does not correspond with the ability to appeal from an inpatient provider, such as a Skilled Nursing Facility (SNF) or hospice. This might be a source of confusion for caregivers as well as beneficiaries. Additionally, the Medicare Advantage (MA) appeal process, which this appeal process was modeled after, does not create this distinction between in-patient (SNF) and outpatient provider (HHA and CORF) termination of service appeals.

How does CMS define "certification" and "significant risk" as is used in this provision?

Does this mean that the beneficiary cannot appeal unless he/she has a note from their doctor, or is the physician the only one that can appeal this termination of services? Can the beneficiary appeal and then try to get their own physician to certify the significant health risk? This "significant health risk" terminology (and provision) does not exist in any of the other appeals processes, and puts an unworkable constraint on filing an appeal for termination of services from a non-residential provider (i.e., HHA or CORF), especially within the time frames that are mandated for the beneficiary to file their appeal.

I currently work for a QIO, in the appeals department and noticed that, to date, under Grijalva, we have not had any appeals from a CORF, and the appeals that we have had from HHA, most of them were due to lack of authorization for additional days that were authorized as soon as the appeal was filed. Of the appeals that went through to completion, none were required to have the physician "certify a significant health risk" to the beneficiary" for the beneficiary/representative to appeal.

Recommendations: If you were to remove the language differentiating between in-patient and out-

patient provider termination of service appeals and remove the language requiring a physician to certify that the termination of services is likely to place the beneficiary's health at significant risk, then the language and appeal process would match the appeal process currently in place, effective and practicable in the Medicare Advantage appeals process.

Issue Identifier: §405.1204

Issue: Paragraph (d)(2): Upon request, the QIO must furnish a copy of the records that it sends to the QIC, by the close of business of the first day after the material is requested by the beneficiary, to the beneficiary (paraphrasing).

Comments: Currently, the QIO's responsibility in providing records exists with the QIO's responsibility to redact (de-identify) all providers' names in the records since the QIO does not have the authority to release the names. The time required in copying the record and redacting all the names from the record would exceed the timeline dictated by this regulation. While it is difficult to predict how many requests for a copy of the medical records that the QIO relied upon while making its determination, this proposal places an unworkable burden on the QIO to produce records (medical records are, on average, 100-150 pages in length for the MA appeals) by the close of the first business day after which they are requested.

Recommendation: The time period for providing the records, as requested by the beneficiary, should be more flexible to allow the QIO time to redact the records and verify that no breach of confidentiality will happen once the records are sent. The proposed regulation should be changed to match the current rules governing the beneficiary's request for a copy of record, to be done as expeditiously as possible.

Thank you for considering these comments on your new proposed changes in the regulations governing the new appeals process.

Sincerely,

Diana Smith, RN

CMS-4004-FC-9 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Ms. Wendy Dupuy, RN** **Date & Time:** **01/24/2005**

Organization : **Visiting Nurse Services of Michigan**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

Regarding the two day notice; what is the process when doing a phone discharge?
What if it is the patient's choice for discharge?
Would the 2 day notice be required if the discharge date was following the original Plan of Care, ex. 6 visits and discharge?

CMS-4004-FC-10 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Mr. Alfred Chiplin** **Date & Time:** **01/24/2005**

Organization : **Center for Medicare Advocacy, Inc.**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-4004-FC-11 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Jan White** **Date & Time:** **01/25/2005**

Organization : **Beverly Enterprises**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4004-FC-11-Attach-1.DOC

Comments to Final Rule on Expedited Determination Procedures for Provider Service Terminations, November 26, 2004

Expedited Determinations (Proposed 405.1200)

"…In order for a beneficiary to request an expedited review, the beneficiary must have received notice that: (1) A provider intends to terminate services and a physician must certify that termination of services is likely to place the beneficiary's health at significant risk; or (2) the provider intends to discharge the beneficiary from an inpatient provider setting."

* For SNF settings, does discharge mean physical discharge from a SNF or discharge from Medicare? A beneficiary could have Medicare coverage terminated and remain in the facility, but it would be uncommon for a beneficiary to be involuntarily discharged from the facility. Our interpretation as an inpatient provider would be physical discharge from the SNF similar to discharge from a hospital, but believe this needs to be clarified.

* For termination of services, are there specific requirements for the content of a physician's certification of health risk?

Analysis and Response to Public Comments

"The primary change involves the establishment of a requirement for a simple, standardized, largely generic notice to each beneficiary before a discharge or service termination. We believe that this termination notice will ensure that all beneficiaries know that Medicare coverage of their provider services is about to end and are aware of their associated appeal rights."

* Does this notice apply to terminating Medicare services in a SNF, or only discharge from the SNF? Section 405.1200(b) requires notice of termination of Medicare coverage of services in a SNF as well as other provider settings. It sounds like this notice is required even if a beneficiary is not being discharged from a SNF. Clarification is needed here.

* The standard termination notice addresses an immediate appeal by the QIO. Does this negate a beneficiary's right to a demand claim sent to the intermediary for review in this situation? The right to a regular review by the intermediary is not mentioned.

* Section 405.1200 (c) requires that a beneficiary sign a notice to be valid. If this applies to terminating Medicare coverage in a SNF setting, there is a concern about the requirement. Many SNF patients have a responsible party acting on their behalf who is not always accessible to sign a notice. Some responsible parties live out of the area and some rarely visit the facility. There needs to be a mechanism for notifying a beneficiary's responsible party by phone and following that up with a mailed written notice like the SNF notices of noncoverage. A SNF may not be able to control whether a denial notice is

signed and/or returned when a responsible party receives it.

* The detailed notice should include an explanation of why services are no longer covered, the applicable Medicare rules and any specific beneficiary information. It would be helpful to clarify your expectations for the detailed notice. How detailed an explanation is expected? Should Medicare coverage rules be quoted from the CMS Manual similar to notice of noncoverage denial paragraphs? What specific beneficiary information would you expect to be included in the detailed notice? Guidelines for completion of this form with examples for each provider type would be beneficial.

* There seems to be different information related to the time requirements for submitting records to the QIO. Page 69258 says providers must submit records by the close of business that they are informed of the request by the QIO. On page 69259, it says a provider must submit documentation by the close of business the day after the day it is notified by the QIO. Is the required documentation different in these cases? If so, can you explain the difference?

* A new notice would be used instead of ABNs for informing beneficiaries of expedited appeal rights. Can you explain the relationship of the new notices to other notices such as notices of noncoverage, ABNs, and NEMBs? Specifically, will the general notice of termination of Medicare coverage take the place of all other notices that would currently be used for that purpose in all applicable provider settings? Or will this notice only be used when discharging from a residential provider or terminating services for non-residential providers and other notices will be required for other scenarios? The relationship of all notices is unclear.

CMS-4004-FC-12 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Mrs. Rachel Hammon** **Date & Time:** **01/25/2005**

Organization : **Texas Association for Home Care**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4004-FC-12-Attach-1.DOC

CMS-4004-FC-13 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Dr. Mansel Kevwitch** **Date & Time:** **01/25/2005**

Organization : **Cascade Urology**

Category : **Physician**

Issue Areas/Comments

Issues

Overview Statutory Changes

Dear Sirs:
I am writing to comment against the deletion of codes 5200 (Cystoscopy) 55700 (Prostatic needle Biopsy) and 52281 (Cystoscopy with urethral dilation) from the list of approved Ambulatory Surgery Center Procedures. While cost containment is a laudable goal, the deletion of these three codes from the current ASC list of approved procedures will detract from patient care and will present a threat to Patient health and safty. 52000 It is notuncommon to do diagnostic cystoscopy only to find significant pathology that requires therapeutic intervention such as biopsy, resection, dilation, or other invasive treatment. In many cases that intervention can be addressed at the of the cystoscopy.
52281 Cystoscopy with dilation: This is a very painful and often very complex procedure requiring specialized equipment, diators, personnel, as well as sedation and often full anesthcsia. It is simply not a procedure that can be done in an office setting routinely. Removing this option for management of urethral strictures would be a great disservice to patients and Urologists.
55700 Prostatic needle Biopsy There are at least 12-20 seperate biopies. This procedure often includes intravenous sedation. It is unreasonable in today's medical logal climate to expect Urologists to administer intravenous sedation without appropriate safeguards available only in an ASC or hospital setting.
In conclusion, the decision to delete codes 5200,52281,55700 is not supported by any Urologic organization and opposed by nearly every colleague I speak with. Removing these codes is couonterproductive and removes options for efficient and cost effective humane management of many medical conditions. I urge you to reconsider and reinstitute 52000,52281 and 55700 as ASC apporved procedures.

Respectfully submitted,
Mansel Kevwitch, MD

January 25, 2005

Centers for Medicare and Medicaid Services
Attention: CMS-4004-FC
P. O. Box 8016
Baltimore, MD 21244-8016

Dear Sir or Madam:

Thank you for the opportunity to comment on the final rule entitled "Medicare Program; Expedited Determination Procedures for Provider Service Terminations" published in the Federal Register on November 26, 2004 (Volume 69, No. 227, Page 69252). The Illinois Home Care Council (IHCC) is a trade association representing approximately 200 home care providers and suppliers in Illinois. These comments were developed by IHCC's Regulatory and Reimbursement Committee.

Regulatory Impact Statement

IHCC believes that CMS has seriously underestimated the financial and administrative burdens that implementation of these regulations will place on home health providers, who do not operate in an institutional or inpatient setting. Specifically, CMS estimates that delivery of the Notice of Medicare Provider Non-Coverage will require approximately five minutes of staff time costing no more than $2.50 per instance.

The five minute time frame used by CMS is far from realistic in the home health environment. Delivery of a written notice requires a visit to the beneficiary's home by a home health agency staff person. When a confused or incompetent patient is involved, it will involve coordinating the visit with a family member or other caregiver. Hours, not minutes, are involved in these situations, including travel; time spent coordinating the visit and time spent with the patient explaining both their options and responsibilities.

Also, CMS has chosen only to estimate the financial burden of delivery of the first notice. No attention is given to the other requirements in the final regulation, including the need to produce and deliver documents to the QIO within a very short time frame; the requirement to prepare and send a detailed termination notice to the patient should he request an expedited review; and the requirement to provide the beneficiary with a copy of the materials sent to the QIO. These activities require staff time and the expenditure of resources for faxing, overnight mailing, and potentially a second uncompensated visit to the patient's home.

Should the beneficiary seek an expedited reconsideration from the QIC, the provider will have to review the clinical record and materials already submitted to the QIO and then determine whether additional materials should be submitted to the QIC as evidence. If the decision is to submit additional evidence then it must be copied and delivered, again, within a very short time frame. These activities entail costs

in both resources and the time of professional and clerical staff.

CMS has also neglected to consider the costs of training staff to deliver and explain the new notices, and to follow the procedures required to implement the provider responsibilities in the event of an expedited review.

Finally, CMS' time frames assume the availability of both professional and clerical staff seven days per week. While the vast majority of home health agencies provide clinical services on weekends, few are staffed with clerical employees. Even if clerical employees are on duty during the weekend, there is rarely enough staff available to add these intensive and time sensitive activities to their assigned duties

To summarize, CMS' burden estimate truly fails to assess the financial and administrative burdens of the final rule for any provider to which it applies. Unfortunately the failure is even more complete when the special challenges of providers who serve beneficiaries in their homes are considered.

Section 405.1200 Notifying beneficiaries of provider service termination

While IHCC recognizes that CMS requirements in this area have their foundation in statute, we find the time frame for delivery of the required notice to be completely unrealistic in the home health setting. Requiring notice two days or two visits prior to termination can be difficult in an inpatient setting, but in the home health setting will often be impossible.

While some patients are discharged from home care at the end of a planned number of visits or elapsed time, many are discharged because they no longer meet the primary eligibility requirements of the benefit. Agency staff may find that the patient is no longer homebound. The physician may discharge the patient from home health care during an office visit even though additional visits were included in the original care plan. A patient may be discharged because she has been admitted to the hospital and the 60 day episode she was in has expired. A managed care company may refuse to approve services that the agency believes the patient needs.

Issuance of a termination notice two days or two visits prior to discharge from home care is virtually impossible in the circumstances described above. If the notice is not delivered according to the unrealistic time frame and circumstances required by the rule, the provider will continue to be financially liable for provision of services to the beneficiary. This may be the case even if the beneficiary no longer meets Medicare's eligibility requirements for home health services.

Section 405.1202 Expedited determination procedures

This section of the proposed rule states that in order to be eligible for an expedited determination a physician must certify that the beneficiary's health will be at significant risk if the services are no longer provided (405.1402(a)(1)). IHCC has noted significant problems with CMS' expectations for implementation of this requirement.

First, the notice available at CMS' website designed to implement this process (Form No. CMS-10123) does not mention that a physician certification is required in order to request an expedited review of the discharge. Who is expected to inform the beneficiary of this requirement, and to explain how the certification is to be documented and transmitted to the QIO? IHCC is concerned that CMS will expect providers to provide this information, which will further inflate the burden estimate. If a physician's certificate is required, why does the notice not say so?

Second, the regulation provides no information about the standard(s) the QIOs will use in evaluating physician certifications that the beneficiary's health will be at significant risk absent the terminated services. Is the physician required to provide some clinical data to back up his statement, or is the statement alone sufficient to support the review request? If providers are not informed about the standards the QIOs will use to evaluate the certifications they will not be able to fully assess what information to provide to the QIO to make their case for discharge.

Section 405.1202(d) states that the burden of proof falls to the provider to demonstrate that the termination of services is appropriate, "either on the basis of medical necessity or based on other Medicare coverage policies." This language presents several problems.

In some instances termination of services to a home health patient is not strictly based on medical necessity or Medicare coverage policies. These include concerns about the safety of an agency staff person providing services in the home and a patient's failure to comply with treatment or medication orders. CMS should clarify how the QIOs and QICs will be instructed to evaluate these issues when considering termination appeals.

Second, without information about how the physician certification of harm will be evaluated by the QIO it is difficult to envision how to structure an argument for termination based on medical necessity. Whose definition of medical necessity will the QIO value most, the physician's evaluation of his patients' needs or the Medicare version delivered by a home health agency that is placed in the middle?

Trying to pair medical necessity with some of the more restrictive aspects of Medicare coverage policy sometimes leaves home health patients in a vulnerable position, such as when the patient continues to have a skilled need, is no longer homebound, but has limited access to transportation needed to secure services on an outpatient basis. When CMS places the burden of proof on the home health agency in these instances it potentially establishes a false conflict between the beneficiary and the provider when, in fact, it is Medicare policy that is causing the patient to have an unmet need.

Finally, it is unclear how the new notice relates to the Medicare Advance Beneficiary Notice for Home Health Agencies (HHABN) currently required when an agency believes that Medicare will not cover a service ordered by the patient's physician. The new notice cannot fully replace the HHABN because it is not designed for situations where services are being reduced but not terminated, or are initially ordered by the physician. Additional consideration and guidance are needed to resolve this conflict.

IHCC believes strongly that CMS should withdraw this final rule define a clearer and more practical

process for providing expedited appeal rights to beneficiaries receiving home health services. At the very least, home health providers should be exempted from this regulation because it will be virtually impossible to implement in the home health setting. CMS must design a workable process that allows home health patients and agencies an opportunity to communicate in a reasonable way that gives providers an adequate chance to provide information to the QIO should an expedited review be requested and granted.

Sincerely,

Thomas Galluppi
President
CMS-4004-FC
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CMS-4004-FC-14 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Mr. Tom Galluppi** **Date & Time:** **01/25/2005**

Organization : **Illinois HomeCare Council**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4004-FC-14-Attach-1.DOC

CMS-4004-FC-15 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Ms. Vicki Hoak** **Date & Time:** **01/25/2005**

Organization : **Pennsylvania Homecare Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-4004-FC-15-Attach-1.JPG

CMS-4004-FC-16 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Miss. Lynn Leighton** **Date & Time:** **01/25/2005**

Organization : **The Hospital & Healthsystem Assoc. of PA**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4004-FC-16-Attach-1.DOC

CMS-4004-FC-17 Medicare Program; Expedited Determination Procedures for Provider Service TerminationsSubmitter : Dr. Date & Time: 01/25/2005 Organization : Dr. Category : Other Health Care Provider Issue Areas/Comments GENERAL GENERAL Please see attachment that specifies where the comments apply. CMS-4004-FC-17-Attach-1.DOC

Comments on Final Rule, 42 CFR 405 and 489

"Analysis and Response to Public Comments"
A. Comments on the Expedited Determination Procedures Required by Section 1869 of the Act:

* In this section, it is noted that there are two additional requirements—the need to provide a detailed notice of why a patient is being discharged and that the notice has to be given two days before the pt's liability begins. Since the rules only apply to non-hospital facilities, but hospital issues are addressed in 42 CFR §405.1206, close by the info on non-hospital facilities, it would be helpful and clarify questions if it is stated that these two aspects do NOT apply to hospital providers, and that their own requirements still apply.
* At present, QIOs do not use only telephonic information to make a determination about beneficiary level of care; for inpatients, the hospital records are required, and similarly care records are required for non-inpatient appeals for MA patients. What guidance will CMS provide to QIOs re: what would be acceptable telephonic information, how will the QIO be expected to verify the information (vs the provider sharing verbally only certain parts of the info, etc) and who will be the source on which the QIOs rely—the patient? the attending physician? the beneficiary/rep? What if this info conflicts?

B.Comments on Procedures for Expedited Reviews of Inpatient Hospital Discharges

* It is stated on page 69260, middle column, that "in keeping with our current policies, QIO determinations are binding on hospitals, without further appeal." However, QIO Manual section 7410 states in part A: "…A beneficiary, provider or practitioner dissatisfied with your denial determination may obtain a reconsideration of the following issues—reasonableness, medical necessity… appropriateness of the setting in which the services were…to be furnished." If you do not consider a QIO determination regarding continuation of services to be a reconsideration under this part, but want to apply the standard of QIO Manual part 7040 A, this should be specifically stated.

B. "Expedited Determinations Procedures"
* The rationale for the costs does not seem consistent with our experience of the cost of carrying out these types of reviews for MA patients. Cost data from that experience, esp. re: QIO work, should be collected and analyzed before finalizing estimates of costs for this new program.
* Will QIOs be expected to handle BIPA appeals on weekends? After hours? This needs to be specified, as it is not clear in the description or the actual regulations.
* If under these new regulations, a patient does not have a physician certify that termination of services may place the beneficiary's health at significant risk, does that mean they cannot appeal their service termination? (Also see §405.1202(a)(1) on this issue.) If this is the case, how is the physician certification expected to be obtained? Who has to obtain this—the provider? The patient? This would be awkward for the beneficiary, especially in a non-residential setting.

D. §405.1204 Expedited Reconsiderations

* Under (d), “Responsibilities of QIO,” it is stated that the QIO must supply all information that the QIC needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the QIC notifies the QIO of the request for an expedited reconsideration.” Since the QICs are expected to be regionally located, rather than in each state, how is the QIO expected to do this the same day as the request? Will the documents need to be faxed? What if same day service is not available? Will there be weekend/after hours requests to the QIO by the QIC? This needs to be clarified.

CMS-4004-FC-18 **Medicare Program; Expedited Determination Procedures for Provider Service Terminations**

Submitter : **Date & Time:** **01/26/2005**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I have also submitted these comments as an attachment. Not sure it went through, so here are comments category by category.

CMS-4004-FC-18-Attach-1.DOC

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