

history of congestive heart failure, hypertension, Type II diabetes, nephrectomy, shortness of breath, palpitations, headache, dizziness, lightheadedness, obesity, and abdominal pain. Prior to the dates of service at issue, the beneficiary had been diagnosed with swelling and erythema of his lower extremities for approximately two months. The beneficiary was previously hospitalized from February 14-23, 2007 for possible cellulitis and was placed on intravenous antibiotics, followed by a two-week course of oral antibiotics following discharge. On March 14, 2007, the beneficiary's podiatrist gave the beneficiary trigger point injections for continued pain.

In a follow-up visit on March 23, 2007, the beneficiary's podiatrist referred the beneficiary to the appellant/provider's hospital with a diagnosis of possible cellulitis and for consideration of long-term antibiotic therapy. The beneficiary was admitted as an inpatient for pain management and for treatment of swelling, redness, erythema, and cellulitis. The hospital's infectious disease department immediately ordered intravenous antibiotics and testing to rule out deep vein thrombosis. The beneficiary was discharged on April 6, 2007 with improvement in his cellulitis. It is this inpatient stay for which coverage and liability is before the Council and addressed by this decision.

On December 2, 2007, the beneficiary's admission was denied by MPRO, the Michigan Quality Improvement Organization (QIO). The QIO found that the beneficiary was admitted for swelling and redness of his legs and general body aches in his legs, arms and wrists. He was placed on intravenous (IV) antibiotics, IV pain medications, and oral medications. The QIO found that the inpatient stay was not medically reasonable and necessary on the grounds that there was no evidence that oral antibiotics or oral pain medications had been tried, nor was the extent of the leg swelling and redness noted; thus, the QIO determined, the beneficiary could have been treated with oral medicines in a less acute level of care. The QIO found the provider liable for the costs of the non-covered hospitalization. The QIO reviewed and affirmed its prior decision on February 22, 2008.

By letter dated March 11, 2008, the provider requested a hearing before an Administrative Law Judge. Exh. 7, at 165. The ALJ scheduled a hearing for May 20, 2008. The notice of hearing

informed the appellant that the specific issues to be addressed at the hearing would be -

[w]hether Appellant's claim qualifies for coverage and payment under applicable Medicare laws, regulations, and policies? To the extent applicable, the hearing may also address the issue of whether the limitation of liability provisions of the Social Security Act apply to either the Beneficiary or to the provider of services? Exh. 12, at 178.

Following the hearing, the ALJ issued an unfavorable decision dated May 29, 2008. The ALJ made two major findings: First, the ALJ determined that his decision must be limited to the issue of *liability* for the non-covered services rather than the issue of coverage itself. The ALJ made this finding after quoting from 42 C.F.R. § 478.40; the *Medicare Quality Improvement Organization Manual* (QIO Manual) (CMS Pub. 100-10), ch. 7, sec. 7500; and CMS Ruling 95-1, at 36. Second, the ALJ found that with regard to liability, the appellant knew or should have known that the beneficiary's inpatient stay would be found not medically reasonable and necessary based on the relevant InterQual criteria for inpatient admissions for cellulitis and/or uncontrolled pain.

The appellant filed a request for review with the Council on July 30, 2008. The appellant asserted that (1) it did not notify the patient in advance of admission that the stay would not qualify for Medicare coverage because the patient did, in fact, meet the InterQual criteria for inpatient admission; and (2) the beneficiary's condition had worsened while at home on oral antibiotics and his pain had not been relieved through oral pain medications. On April 10, 2009, the Council remanded this case to the ALJ because it had not obtained the complete record, including the hearing recording, from the ALJ. However, the complete record has been located and forwarded to the Council; thus, the Council vacates its prior remand order and proceeds to address the request for review.

DISCUSSION

1. The Extent of ALJ and Council Jurisdiction

In his decision, the ALJ found that the appellant, as a provider of services, was limited in the scope of its appeal of the QIO

decision to the ALJ. Citing to 42 C.F.R. § 478.40, CMS Ruling 95-1, and the Medicare Quality Improvement Organization Manual, ch. 7, sec. 7500, the ALJ found that the appellant could not appeal the QIO's finding that the inpatient admission was not medically reasonable and necessary; rather, the ALJ found, the appellant was limited on appeal to the issue of limitation of liability under section 1879 of the Act. Thus, while the provider had appealed the overall denial of the claim (presumably including both coverage and liability), and while the ALJ had stated in the notice of hearing that coverage was an issue before him, the ALJ declined to address coverage on jurisdictional grounds in his decision. The ALJ found that the appellant was liable for the cost of the non-covered services, as found by the QIO.

The Council notes that the authorities cited by the ALJ are interpretations of section 1155 of the Act, which historically provided that any *beneficiary* dissatisfied with a determination of a QIO could appeal to an ALJ if the amount in controversy following the QIO reconsideration was \$200 or more. Section 1155 did not extend such right to appeal to the ALJ level to a provider or supplier of Medicare items or services, but was instead silent on such matter. CMS, through the authorities cited by the ALJ, clarified that only beneficiaries, but not providers or other practitioners, could appeal an unfavorable QIO decision to an ALJ.

However, with the passage of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Congress significantly changed the appeals process to create a uniform process for Medicare Part A and Part B appeals, which was phased in beginning in 2005. BIPA, Pub.L. 106-554, § 521, 114 Stat. 2763A (2000). Pursuant to these statutory changes to section 1869 of the Act, the Secretary of Health and Human Services promulgated new appeals regulations at 42 C.F.R. Part 405, Subpart I (405.900 *et. seq.*). In the preamble to such regulations, CMS stated that, "we believe that the interests of the appeals process would be best served by ensuring that providers are afforded an equal opportunity to be heard with regard to all Medicare initial determinations . . . we are specifying that Medicare providers may file administrative appeals of initial determinations to the same extent as beneficiaries." 70 Fed. Reg. 11420, 11427 (March 8, 2005).

In an August 17, 2009 letter to the Council from the HHS Chief Counsel, Region V, the Office of General Counsel (OGC), speaking for both HHS and CMS, stated that it was HHS's position that section 1155 of the Act and its corresponding regulations "should not be read in isolation" given the subsequent BIPA legislation and implementing regulations. The OGC Chief Counsel cited the Supreme Court, stating that "[o]ver time, . . . subsequent [A]cts can shape or focus [the statute's meanings]. The 'classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.'" FDA v. Brown & Williamson Tobacco, 529 U.S. 120, 143 (2000), (citing United States v. Fausto, 484 U.S. 439, 453 (1988)). OGC further asserted:

Arguably, enactment of section 521 of BIPA could constitute an implied repeal of section 1155 of the Act insofar as it appears to be in irreconcilable conflict with the earlier provision, covers the whole subject of the earlier provision, and seems clearly intended as a substitute. (citation omitted)

Applying the more-recent section 1869 regulations in this case would give effect to the broad legislative changes enacted by Section 521 of BIPA, changes that were meant to provide a uniform appeals process for Medicare Part A and Part B claims and to expand provider appeal rights. Applying section 1155 and its related regulations creates a separate and more limited appeals process for providers, a result that appears to directly contradict BIPA and the revised 1869 regulations.

Because HHS has taken such a position with regard to its appeals regulations and policy statements, the Council finds that section 1155 and its implementing regulation and policy guidelines were not binding on the ALJ in light of the recent BIPA law and new appeals regulations at 42 C.F.R. Part 405, Subpart I. The new law and regulations collectively provide that either a provider/practitioner or a beneficiary may appeal both the findings on coverage and liability to an ALJ following an inpatient hospital admission denial by a QIO, if at least \$100 remains in controversy. See, generally, 42 C.F.R. §§ 405.906, 405.924(b)(11), 405.1002, and 405.1006(b)(1). Thus, the

Council finds that the ALJ was not restricted to addressing only the limitation of liability in the provider's appeal of this unfavorable QIO decision. The Council will thus address both the coverage as well as limitation of liability issues in this decision to the extent they are applicable.

2. Coverage

The Council notes that the ALJ held a hearing in this case at which multiple witnesses of the provider testified. The central issue on which the ALJ focused and issued a decision, and on which the appellant provided testimony, was whether the patient's admission met the InterQual criteria based on either a diagnosis of cellulitis or uncontrolled pain. The ALJ found that the patient did not meet the InterQual criteria for either diagnosis and, thus, the provider knew or should have known under section 1879 of the Act that the inpatient admission would not be covered by Medicare. While the ALJ specifically made findings on only the limitation of liability issue, the issue of coverage was inexplicably intertwined with the issue of coverage in the ALJ's analysis: if the beneficiary did not meet the InterQual criteria, then the services would not be medically reasonable or necessary, and the provider should have known, based on the failure to meet admission criteria, that the services would be covered. If, on the other hand, the beneficiary did meet the InterQual criteria for admission, then the services could be considered medically reasonable and necessary and covered by Medicare, and limitation of liability would be irrelevant.

Because the provider offered extensive testimony regarding the patient's condition and its relationship to the InterQual criteria, the Council finds that the appellant was not prejudiced by the ALJ's lack of specific findings on the coverage issue. Moreover, because the Council is reversing the ALJ's overall decision and finding that the appellant sufficiently met the InterQual criteria for admission, the Council finds that there is no prejudice to the provider if the Council does not remand this case to an ALJ for a finding on coverage.

The InterQual criteria for inpatient admissions are proprietary industry guidelines for acute care hospital admissions and are widely used by acute care hospitals in making inpatient admission decisions. As the ALJ noted, the InterQual criteria

are not developed by CMS and are not binding on CMS for coverage purposes. However, the regulations at 42 C.F.R. § 411.406 state that an appellant is charged with constructive knowledge of Medicare coverage criteria provided via receipt of CMS notices, including manual issuances, bulletins, or other written directives from contractors, "including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO." 42 C.F.R. § 411.406(e)(1). While the QIO did not specifically reference the InterQual guidelines in denying coverage for the inpatient admission at issue or in any of its determinations, the ALJ found that the QIO had previously adopted InterQual criteria. Given that the QIO did not reference any other sources in finding that the inpatient admission at issue was not medically reasonable and necessary, the Council will be guided by the InterQual criteria applicable to this patient's conditions.

In its November 21, 2007 letter to the QIO, the provider identified the InterQual criteria for inpatient admissions with a diagnosis of cellulitis as requiring an infectious disease requiring parenteral anti-infectives or post-surgical management or both, including continued medical management of the primary condition (cellulitis). The provider identified the InterQual inpatient admission criteria for pain management as a medically complex condition/illness requiring continued medical management of the primary condition/illness, with uncontrolled pain. The provider argued throughout this appeal that the beneficiary needed IV antibiotics and IV pain medication (morphine) with an IV-push, and needed treatment for both the cellulitis and severe pain. In his decision, the ALJ found that the beneficiary did not meet these criteria on the ground that the beneficiary had not been tried on oral antibiotics and oral pain medications prior to this admission to the hospital. The provider responded that the beneficiary had been treated on oral antibiotics and pain medications prior to the inpatient admission.¹

¹ In its request for review, the appellant also asserted that the beneficiary needed to be admitted to the hospital for the morphine treatment, in part, because of "his past history of IV drug abuse." The Council has found no references to such history of drug abuse in the medical records. The admission database intake form dated 3/23/07 notes that the beneficiary's only (current) substance use is cigarettes. Exh. 1, at 65. Thus, the Council will not consider any alleged history of drug abuse in assessing admission criteria.

The Council finds that there is sufficient evidence in the record on which the provider hospital reasonably determined that the patient could be admitted as an inpatient. The record establishes that at the time of admission on March 23, 2007, the beneficiary had been experiencing erythema, swelling and redness of the lower extremities for several months. The beneficiary had been already been admitted to the hospital for nine days to treat this condition on February 14-23, 2007, approximately one month earlier. There, the beneficiary received IV antibiotics, followed by a course of oral antibiotics at home for two weeks following discharge. Nonetheless, the pain, swelling and redness returned or escalated within such a short time that the beneficiary's podiatrist referred the beneficiary back to the hospital exactly one month following his prior admission for consideration of long-term antibiotic treatment. Once admitted, the provider's infectious disease department ordered the immediate infusion of IV antibiotics. When the beneficiary was discharged approximately two weeks later, the cellulitis was much improved.

While the medical records do not specifically identify that the beneficiary was taking oral pain medications at home prior to his admission on March 23, 2007, the Council finds that the record so thoroughly documents the extent of his pain to make such admission justified. During the two weeks in the hospital, the beneficiary received many different narcotic medications, including several opium derivatives. These pain medications included Morphine (IV), Dilaudid (hydromorphone), Vicodin (hydrocodone), and Oxycontin (oxycodone). Yet despite these strong narcotic pain medications, the beneficiary's pain widely fluctuated during his inpatient stay, and he frequently reported that the pain was severe and only relieved for a few hours at a time. This does not suggest a patient whose pain could have been controlled in an outpatient setting. Given the beneficiary's medical conditions and history including obesity, diabetes, congestive heart failure, high blood pressure, nephrectomy, and shortness of breath, the Council finds that the beneficiary's inpatient admission met criteria for coverage.

Because the Council finds the inpatient hospital admission covered by Medicare, the Council need not reach liability under section 1879 of the Act.

DECISION

It is the decision of the Medicare Appeals Council that the beneficiary's inpatient stay of March 23, 2007 through April 6, 2007 was medically reasonable and necessary and met coverage criteria. The Council reverses the ALJ decision.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Susan Wiley
Administrative Appeals Judge

Date: October 27, 2009