



July 22, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9993-IFC2, Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes

FILED ELECTRONICALLY at <http://www.regulations.gov>

Dear Dr. Berwick:

The National Coalition for Cancer Survivorship (NCCS), representing survivors of all forms of cancer and advocating for quality cancer care, is pleased to offer comments on the interim final rules on internal claims and appeals and external review processes. We commend the three agencies (the Departments of Health and Human Services, Labor and Treasury) for their diligent joint work on these important regulations given their significant implications for patients' ability to obtain needed health care services and health coverage. There are, however, a few areas of the interim final rules where NCCS has concerns. Namely, we are concerned that certain of the revisions of the interim final rules originally issued in 2010 will restrict the ability of cancer survivors to appeal denials of coverage and could have an adverse impact on the quality of cancer care delivered to many Americans.

Timeline for Benefit Determination for Urgent Care

The interim final rules would extend to 72 hours, from the 24-hour deadline set out in 2010, the time that plans or issuers have until they must notify a claimant of a benefit determination for urgent care. In making the decision to lengthen the time for action by plans, the agency identifies the concerns of commenters that the 24-hour rule had the potential to harm claimants because such a review might be rushed and of compromised quality. The agency also states that commenters cited the Emergency Medical Treatment and Labor Act (EMTALA) as a protection for patients who need emergency care without preauthorization.

Although the modification of the deadline for benefit determination from 24 to 72 hours will not have an adverse impact on many cancer patients who need not initiate treatment immediately upon diagnosis, for others the delay of a determination could mean a corresponding delay in initiation of life-saving care. For certain patients with acute hematological malignancies, Burkitt's lymphoma, and some types of testicular cancer, a 72-hour delay in receipt of care could have a negative effect on outcomes. In addition, for those patients, the protections of EMTALA are not sufficient because those patients require initiation of treatment without delay and not simply a stabilization of their condition, as required by EMTALA.

In describing its decision in 2010 to propose a 24-hour deadline, the agency cited improvements in electronic communication that would support a more rapid claim determination process. We agree that health plans and issuers should be encouraged to utilize technology to make benefit determinations for urgent care within 24 hours. That deadline should not be unreasonably burdensome for plans and provides beneficiaries greater assurance that their care will be provided in a timely fashion.

Scope of Federal External Review Process

The scope of review defined in the interim final rules is significantly more limited than that set forth in the 2010 interim final rules. By limiting federal external review to claims that include medical judgment or a rescission of coverage and specifically excluding review of legal and contractual issues, the agency severely restricts the protections provided to beneficiaries.

According to examples provided in the preamble and also included in the interim final rules, review of decisions about out-of-network care would be considered issues of medical judgment only in those circumstances where the plan stipulates that out-of-network coverage will be available if the service cannot be provided in-network. Cancer patients – including but not limited to those with rare forms of cancer or rare subtypes of more common forms of cancer – frequently find that they need care provided only out-of-network and that the care that may be available to them in the plan network is inappropriate or inadequate. The issue of out-of-network care becomes essentially a matter of medical necessity and appropriateness and should be subject to external review without the limitations included in the revised rules. We urge that the language related to the scope of external review be amended to include review of all decisions related to access to care outside a health plan's network.

Parenthetical language in the rules identifies several issues of medical judgment that are within the scope of review; these include the plan's or issuer's "determination that a treatment is experimental or investigational." We wish to underscore the importance of including such decisions within the scope of external review. Beneficiaries have often found themselves in the position of disputing the determination of plans and issuers that their care or certain elements of it are "experimental," and therefore not covered according to the terms of their insurance contract. Plans and issuers exercise wide discretion in classifying care as "experimental," and in the past cancer patients have disputed the "experimental" classification of care in a clinical trial or evidence-based off-label uses of drugs, among other critical elements of cancer care. It is critically important that decisions about access to investigational care be considered issues of medical judgment and therefore subject to review, regardless of plan language related to coverage of investigational care.

We note that the agency intends to assess the implementation of the external review process standards, with the possibility of restoring the terms of the 2010 rule in the future. We urge that the change recommended above related to out-of-network care and the clarification related to investigational care be made immediately, and we look forward to the agency's assessment of the external review standards, which may support additional modifications.

Provision of Culturally and Linguistically Appropriate Notices

We appreciate the difficulty of balancing the cost and burden of providing notices in non-English languages against the need of those who are not literate in English to receive proper notices. Establishing a trigger (ten percent of those who are of limited English proficiency, as judged by the demographics of the county) for providing notices in non-English languages is identified by the agency as an approach that balances competing needs. However, the threshold approach will leave many individuals and populations without access to culturally and linguistically appropriate notices.

We recommend that the rules be revised to determine thresholds for translating notices based on plan demographics rather than county demographics and that there be a numeric threshold of 500 in addition to a percentage threshold. Moreover, we recommend that oral communication services be provided for those who request them, even if the thresholds for translation of written documents are not met. Many nonprofit cancer service organizations routinely provide communication assistance to those with limited English proficiency who seek to take advantage of their services. These organizations find that such communication assistance services are readily available at a cost that is appropriate for the benefit provided to cancer patients and consistent with the budget of the nonprofit agency. We urge that the standard of service adopted by nonprofit service organizations also be adopted in the interim final rule and required of plans and issuers.

We appreciate the opportunity to offer comments on the interim final rule and urge the agency to consider revisions that are responsive to the needs of individuals with cancer and others who require intensive treatment for their disease, including treatment on an urgent basis in the case of certain acute cancers.

Sincerely,



Nicole H. Tapay
Senior Director of Policy
National Coalition for Cancer Survivorship

NHT/vb