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Recent Developments in the Medicare Program

By Kim Glaun, Vicki Gottlich, and Rochelle Bobroff

In the past year the Medicare program has been subjected to judicial, statutory, and regulatory changes. In this article we highlight and summarize these recent developments. In section I we discuss new Supreme Court precedent related to jurisdictional requirements in administrative and federal court practice. In section II we evaluate recent proposals to modify how national coverage is determined. In section III we review the new prospective payment system for hospital outpatient services.1 In section IV we report on new developments in the Medicare+Choice program as a result of new regulations, the Balanced Budget Refinement Act of 1999, and the approval of the first Medicare+Choice private fee-for-service plan by the Health Care Financing Administration.*

I. Recent Supreme Court Decisions on Jurisdiction

In the 1999–2000 term the U.S. Supreme Court issued two jurisdictional decisions affecting Medicare beneficiaries. In Sims v. Apfel, a case involving social security disability benefits, the Court held that claimants were not required to identify legal issues during the informal, nonadversarial administrative appeals process in order to raise the issues later on appeal in federal district court.3 In another case, Shalala v. Illinois Council on Long Term Care Inc., the Supreme Court held that Medicare providers could not utilize federal question jurisdiction to challenge the legality of nursing home penalty regulations.4

A. Issue Exhaustion

The Social Security Act, 42 U.S.C. § 405(g), provides jurisdiction for judicial review of the Social Security Administration’s “final decision” in Medicare and social security cases. The agency’s decision becomes “final” at the end of the four-stage administrative review process. This process is informal and nonadversarial, and many beneficiaries complete it without representation by an attorney.

In *Sims v. Apfel* a claimant for social security disability benefits alleged in federal district court that the administrative law judge made legal errors in upholding the denial of her application for benefits, but she failed to identify these issues in her request for Appeals Council review. The Fifth Circuit held that, as a result of this failure, it lacked jurisdiction to consider these legal issues, even though the claimant had completed all four stages of administrative review. The Ninth and Tenth Circuits had similarly required “issue exhaustion” at the administrative level in order to preserve the right to judicial review of the legal issues. Shortly after the Fifth Circuit’s decision in *Sims*, however, the Seventh and Eighth Circuits rendered contrary decisions and held that, due to the informality of the administrative process, issue exhaustion was not required.

The Supreme Court granted certiorari in *Sims* to resolve this conflict among the circuits. In a five-to-four decision the Court struck down the issue exhaustion requirement imposed by the Fifth Circuit. It held that section 405(g) conferred jurisdiction upon federal district courts to consider all legal issues, including issues raised for the first time in district court. Issue exhaustion, observed the Court, is usually imposed by statute or regulation, but neither the Social Security Act nor regulations contain such a requirement. The Court noted that the administrative appeals process was informal, and the appeals forms and notices did not require a detailed exposition of legal issues. It concluded that “[t]he Appeals Council, not the claimant, has primary responsibility for identifying and developing the issues. We therefore agree with the Eighth Circuit that ‘the general rule [of issue exhaustion] makes little sense in this particular context.’”

The Supreme Court’s decision in *Sims* is applicable to Medicare cases, and thus lower-court decisions imposing issue exhaustion in the Medicare context are

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7. 162 F.3d 1160 (5th Cir. 1998).

8. See, e.g., *Meanel v. Apfel*, 172 F.3d 1111, 1115 (9th Cir. 1999); *James v. Chater*, 96 F.3d 1341, 1343-44 (10th Cir. 1996).


11. *Zd.* at 2084.

12. *Id.* at 2085-86.

13. *Id.* at 2086, citing *Harwood*, 186 F.2d at 1042. Justice O’Connor’s concurrence focused on the lack of notice to claimants that they had to raise issues before the Appeals Council in order to preserve their right to judicial review. *Zd.* at 2086-87.
no longer valid.\textsuperscript{14} \textbf{Sims} does not discourage attorneys from raising legal errors during the administrative appeal process. Instead the decision permits attorneys to identify new issues when cases reach district court.

\textbf{B. Federal Question Jurisdiction}

Although federal district courts have jurisdiction under 28 U.S.C. §\textsuperscript{1331} to hear “Civil actions arising under the Constitution, laws, or treaties of the United States,” the Social Security Act, 42 U.S.C. §\textsuperscript{405(h)}, states that no action may be brought under 28 U.S.C. §\textsuperscript{1331} “to recover on any claim arising” under the Act. The Supreme Court had previously held that section 405(h) barred federal question jurisdiction to hear procedural challenges involving claims for social security and Medicare benefits, including statutory and constitutional claims.\textsuperscript{15} However, the Court had also held that federal question jurisdiction could be utilized to raise statutory and constitutional challenges regarding Medicare Part B since, at that time, there was no other mechanism for judicial review of these challenges.\textsuperscript{16} Subsequently, however, Congress amended the Medicare Act, 42 U.S.C. §\textsuperscript{1395ff}, to provide expressly for administrative and judicial review of Part B benefit claims.\textsuperscript{17}

In \textit{Shalala v. Illinois Council on Long Term Care Inc.}, an association of nursing home providers challenged the Medicare nursing home penalty regulations; the association alleged that the regulations violated the U.S. Constitution, the Medicare Act, and the Administrative Procedure Act. The case was a \textit{preenforcement} challenge to the regulations and thus did not involve any specific penalty determination. The district court, ruling that it lacked jurisdiction, dismissed the case; the Seventh Circuit reversed the district court’s decision.\textsuperscript{18} The U.S. Supreme Court, in another five-to-four decision, agreed with the district court and reversed the Seventh Circuit.\textsuperscript{19}

The Supreme Court held that the district court lacked jurisdiction under 28 U.S.C. §\textsuperscript{1331} to consider the statutory or constitutional validity of the Medicare regulations.\textsuperscript{*} The Court ruled that federal question jurisdiction was explicitly precluded by the Social Security Act, 42 U.S.C. §\textsuperscript{405(h)}, since the provider could appeal a sanction through the administrative appeals process.\textsuperscript{21} Acknowledging the “delay-related hardship” associated with administrative exhaustion, the Court found nonetheless that Congress had determined such hardship to be “justified.”\textsuperscript{**} The Court concluded: “Proceeding through the agency in this way provides the agency the opportunity to reconsider its policies, interpretations, and regulations in light of those [admin-
As a result, in Medicare cases raising constitutional and statutory claims, plaintiffs must exhaust administrative remedies before seeking judicial review.

II. Recent Proposals to Modify Medicare Coverage Determinations

Medicare national coverage determinations and local medical review policies have a greater effect on receipt of reasonable and necessary care than most national coverage determinations or local medical review policies applied to their cases on the basis of scanty evidence, questionable standards, or stale information.

Elderly clients and clients with disabilities suffer harm when they are precluded from obtaining critically needed medical procedures by national coverage determinations or local medical review policies applied to their cases on the basis of scanty evidence, questionable standards, or stale information.

Medicare beneficiaries and their representatives understand. Elderly clients and clients with disabilities suffer harm when they are precluded from obtaining critically needed medical procedures by

23 Id. at 1099.

24 National coverage determinations are national policy statements by the Health Care Financing Administration regarding which health care services, procedures, or devices the Medicare program will or will not cover and under what circumstances. Such determinations are binding on all Medicare contractors. The agency bases its authority to issue national coverage determinations on the requirement that Medicare pay only for services that are prescribed by a physician and are reasonable and necessary for the diagnosis or treatment of an illness or injury. 42 U.S.C. §1395y(a). Local medical review policies are determinations made by regional intermediaries or carriers with which the agency contracts in the absence of or as a supplement to national coverage determinations. These determinations may vary from one region to another but may not conflict with national coverage determinations.


26 42 U.S.C. §§1395ff(a)(3)(A), (b)(3). Note, however, that the prohibition against administrative law judge review of national coverage determinations does not apply to local medical review policies. Administrative law judges are free to reject, on a case-by-case basis, local medical review policies developed by local carriers.

27 Id § 1395ff(b).
B. Response to Problems with National Coverage Determinations

In December 1998 the Health Care Financing Administration announced the creation of the Medicare Coverage Advisory Committee consisting of outside experts to review certain proposals for national coverage determination. It published a general notice describing a new, more open process for national coverage determination. Since March 2000, the advisory committee’s executive committee has been considering further guidance for Medicare coverage advisory committee panels. In May 2000 the Health Care Financing Administration also issued a notice of its intent to publish proposed regulations concerning criteria for making both national coverage determinations and local medical review policies. Unfortunately several of these recent steps taken to improve coverage determinations may exacerbate existing problems while creating new ones for beneficiaries who seek medically necessary care.

1. Beneficiary Concerns

Beneficiary advocates believe that the process used by the Health Care Financing Administration in making national coverage determinations expanded upon by the Medicare coverage advisory committee’s guidance exceeds the agency’s authority by, for extended periods, depriving beneficiaries of services prescribed by their physicians.

The Medicare statute entitles beneficiaries to a broad range of specific medical services. Generally, if a beneficiary’s physician recommends a medical service, the service is covered. The sole exception is “items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

The key point to the exception is that, before refusing payment, the Health Care Financing Administration must first determine that a service is not reasonable or necessary. Nevertheless, the agency’s, and more recently the Medicare coverage advisory committee’s, guidelines have reversed this approach. The proponents of a service now must not only show why it should be covered but also produce evidence of a certain type and standard that may be unavailable or inappropriate for some procedures or technologies or for the beneficiaries who actually need the service. This shift has often led to substantial delays in the agency’s response to requests for coverage determinations, to the detriment of beneficiaries.

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*Advocates have found creative ways to avoid application of existing determinations; e.g., they argue that certain technologies do not fall within existing noncoverage determinations or that the determination in question was not issued pursuant to 42 U.S.C. §1395y(a)(1) and so may be reviewed by the administrative law judge.

29 64 Fed. Reg. 22619 (Apr. 27, 1999). The notice also announced the withdrawal of proposed criteria for making national coverage determinations; the criteria were published in 1989 pursuant to the settlement of Jameson.
32 42 U.S.C. §§ 1395, 1395d, 1395k.
33 Id. § 1395.
34 Id. § 1395y(a)(1)(A).
of beneficiaries. The Medicare coverage advisory committee’s suggestion that additional outside experts—different from the outside experts who serve on the committee’s panels—be used to evaluate evidence before it is reviewed by the panel would only exacerbate these delays.

2. Concerns with Proposed Criteria for National Coverage Determinations

The Health Care Financing Administration’s stated goal in making coverage determinations is to make Medicare “responsive to rapid advances in health care” and to“facilitate timely and expanded access to appropriate new technologies.” To achieve this goal the agency proposes to ask two questions in determining whether to cover a service or technology: (1) Does the item or service demonstrate medical benefit? (2) Does the item or service demonstrate added value to the Medicare population? The ensuing coverage decision, according to the agency, describes the clinical circumstances and settings under which an item or service would or would not be covered for a clinical subset or class of Medicare beneficiaries.

The approach described in the general notice continues several practices that beneficiaries find problematic. It requires proponents of an item or service to show why Medicare should cover the item or service; reiterates agency’s preference for evidence based upon randomized clinical trials, the most time-consuming and costly approach to scientific data collection; and fails to consider whether other insurance providers cover an item or service, resulting, on occasion, in an anomalous situation whereby certain carriers cover an item or service under their own plan but deny claims for coverage under Medicare.

The notice raises additional troubling issues about how Medicare coverage review will work and how the criteria will be applied. First, the “medical benefit” criterion narrows the scope of reasonable and necessary services by focusing on improvement, even though Medicare currently covers items and services necessary for beneficiaries to maintain their current health or ability to function. Furthermore, the “added value” criterion imposes cost as a coverage factor and is no different from the cost-effectiveness criterion that was included in earlier proposed rules on Medicare coverage criteria that were later withdrawn. The statutory section upon which coverage decisions are based, and which has been in effect without amendment since the Medicare Act was passed 35 years ago, does not provide for a cost-based analysis in determining whether an item or service is “reasonable and necessary.”

In the general notice the Health Care Financing Administration describes both national coverage determinations and local medical review policies as “population-based policies” that apply to a clinical subset or class of Medicare beneficiaries. This has not been the case with

37 In April 2000, a month after the due date under its new procedures, the Health Care Financing Administration agreed to delete a noncoverage determination which classified augmentative and alternative communication devices as convenience items, Medicare Coverage Manual §60-9 (DME Reference List), and to classify them as durable medical equipment covered by Medicare. The agency refused to issue a national coverage determination, as requested by the advocate petitioners, because the substantial evidence they submitted did not include sufficient medical evidence of outcomes and patients who would benefit. The agency authorized carriers to make local coverage decisions about the devices, thereby leaving beneficiaries only slightly better off than they had been.


39 Id. at 31127.

40 Id., e.g., 42 C.F.R. § 409.44(c)(2)(iii) (coverage of home health therapy services to establish a safe and effective maintenance program).


national coverage determinations, which generally apply to the Medicare population as a whole. Limiting all national coverage decisions to certain segments of the Medicare population is a new concept that narrows, rather than expands, access to care. Furthermore, experience with local medical review policies suggests that limiting national coverage determinations to subsets of the Medicare population may promote unnecessary discrimination based on diagnosis or functional ability.

Furthermore, in violation of the Medicare statute, the proposed approach interferes with the practice of medicine. Under the proposed criteria, in considering "added value," the Health Care Financing Administration does not cover an item or service that is equal in effectiveness to an item or service already covered, unless the new item or service is less costly. The agency also has the option of withdrawing coverage if it determines that a new item or service is more cost-effective. As a result, the treating physician loses the ability to determine, in conjunction with the patient, which equally effective item or service is more efficacious for the patient.

III. Medicare Prospective Payment System for Hospital Outpatient Services

The final rule on the prospective payment system for outpatient services went into effect on August 1, 2000. For beneficiaries, the most important change is the eventual reduction in their liability for outpatient services.

A. Calculation of Beneficiary Coinsurance Amounts

The Balanced Budget Amendment required that the beneficiary coinsurance amount for hospital outpatient services eventually equal 20 percent of the Medicare payment rate to hospitals, rather than 20 percent of the provider's billed amount. Under the prospective payment system, coinsurance for a specific procedure is set at 20 percent of the median charges from 1996 (updated to 1999) for each service listed in the ambulatory patient classification group to which the beneficiary is assigned. Coinsurance payment rates that are higher than 20 percent of the ambulatory patient classification amount remains frozen until the annual ambulatory patient classification increases. Although coinsurance will eventually equal 20 percent of the payment rate for the procedure, the regulations on the prospective payment system do not impose a deadline by which this point must be reached. As a result, for certain procedures, beneficiaries will continue to pay significantly more than 20 percent of the Medicare payment amount for decades.

Under the prospective payment system, hospitals may elect to reduce beneficiary coinsurance.
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B. Impact of the Prospective Payment System

The prospective payment system’s goal to reduce beneficiary coinsurance amounts is undermined, in part, by the failure of the regulation to contain deadlines by which coinsurance must equal 20 percent of the Medicare payment rate. Also, the degree of regulatory complexity makes hospital implementation a concern. The manner in which payments to hospitals are calculated under the prospective payment system, and the concomitant incentives to limit costs, may cause certain hospitals to limit or deny access to certain Medicare patients or to reduce the quality of care provided. For these reasons, beneficiary advocates should monitor the implementation of the prospective payment system and encourage the Health Care Financing Administration to monitor quality of care and access to services for beneficiaries receiving outpatient services.

IV. Medicare+Choice Update

Effective July 31, 2000, the Health Care Financing Administration’s final rule on Medicare+Choice contains revisions of the 1998 interim final rule and modifications required by the Balanced Budget Refinement Act of 1999. While the new regulations contain many significant changes, we discuss here only those concerning the following topics: beneficiary eligibility, election, and enrollment; benefits and beneficiary protections; and appeals and grievances.

Also, because the first Medicare+Choice private fee-for-service plan has become available for Medicare beneficiaries in certain states, we review here the regulatory provisions governing such plans.

A. Eligibility for Medicare+Choice

The new rules add certain provisions regarding beneficiary eligibility for the Medicare+Choice program. A new “seamless conversion option” allows Medicare+Choice program beneficiaries to enroll in Medicare+Choice Medicare+Choice private fee-for-service plans.

52 42 C.F.R. § 419.42. Hospitals are allowed to advertise their “discounted” coinsurance amounts for particular services to attract beneficiaries to their facilities. Id.


54 Other areas of change include beneficiary education, plan marketing, and quality assurance standards.

55 In May 2000 the Health Care Financing Administration approved the application of the Sterling Life Insurance Company to offer Medicare+Choice private fee-for-service plans in 17 states (primarily in rural areas) effective July 1, 2000. Sterling has agreed to offer plans throughout Alaska, Idaho, Kentucky, Minnesota, Nebraska, New Mexico, Nevada, Oregon, South Dakota, Tennessee, and Utah and in portions of Arkansas, Louisiana, Mississippi, Ohio, Texas, and West Virginia.

56 The interim final rule generally provides that individuals are eligible to elect a Medicare+Choice plan if they (1) are entitled to Medicare under Part A and are enrolled in Part B, (2) have not been diagnosed with end-stage renal disease, and (3) reside in the service or continuation area. 42 C.F.R. § 422.50.
Medicare+Choice plans to offer enrollment to individuals who, upon becoming eligible for Medicare, live outside of the plan’s service area but are already enrolled in another plan offered by the managed care organization or who have been a member of an employer group health plan that includes the elected Medicare+Choice plan. The seamless conversion option applies to all newly eligible Medicare beneficiaries, including those with end-stage renal disease and persons with disabilities. Plans electing this option must offer the same benefits (including additional and supplemental benefits) to conversion enrollees as to those in the service area through the Medicare+Choice plan’s provider network.

Similarly the final regulations contain new provisions related to services for enrollees who permanently move out of a service area into a continuation service area. Such enrollees must elect in writing to remain with the same Medicare+Choice plan; otherwise the decision to move is treated as a decision to disenroll. Managed care organizations may not impose greater cost-sharing obligations for basic benefits on enrollees in continuation areas than for those in the service area.

B. Election and Enrollment

The new regulations reflect revisions made by the Balanced Budget Refinement Act to the Medicare+Choice election periods set forth in the Balanced Budget Act and the interim final rule. First, the new rules exempt institutionalized enrollees from restrictions on open enrollment periods that will commence in 2002. Thus institutionalized individuals may continue to change freely from original Medicare to a Medicare+Choice plan, from a Medicare+Choice plan to original Medicare, or from a Medicare+Choice plan to another plan when enrollment restrictions begin in 2002.

Second, the new rules add an opportunity for beneficiaries who are subject to managed care organization nonrenewals to obtain guaranteed-issue Medigap protections. Under the Balanced Budget Act, the effective termination date of the plan triggers a 63-day period in which beneficiaries may purchase certain Medigap policies without consideration of preexisting conditions. Section 501(a) of the Balanced Budget Refinement Act extends the Medigap protection period as well to the date the enrollee receives written notice of termination from the plan. Thus the 63-day Medigap protection period now begins either (1) when the plan notifies the enrollee of the impending termination (by October 2, 2000) or (2) upon the effective date of the plan’s nonrenewal.

Third, the Balanced Budget Refinement Act changed the effective date of elections made during open enrollment periods. Now an election made during

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57 42 C.F.R. §§ 422.50 (3)-(4). The provision of such services in continuation areas is subject to access requirements as set forth in 42 C.F.R. § 422.112.

58 Id. § 422.54.

59 See id. § 422.54(c)(2); Operational Policy Letter 99.100.

60 42 C.F.R. § 422.54(d)(1), (d) (3). However, managed care organizations may offer less generous additional or supplemental benefits to enrollees in the continuation area. See 65 Fed. Reg. at 40181.


63 In regard to the first, as required by 42 C.F.R. § 422.506(a)(2)(ii), managed care organizations must give notice to their enrollees at least 90 days before the effective date of the nonrenewal. In regard to the second, see 42 C.F.R. § 422.62(b)(1); Balanced Budget Refinement Act § 501(a)(1), amending § 1851(e)(4) of the Act, 42 U.S.C. § 1395w-21(e)(4); id. § 1882(s)(3), 42 U.S.C. §1395ss(s)(3).

64 “The date of election is defined as the date the plan receives the election form. 42 C.F.R. § 422.68.
an open enrollment period is effective the first day of the following calendar month if made by the tenth of the month. If the election or change in election is made after the tenth, the election is effective the first day of the second subsequent calendar month.65

C. Benefits and Protections

Each Medicare+Choice plan must cover all services included under Parts A and B of traditional Medicare (known as “basic benefits”).66

1. General Requirements

The new rules explicitly state that, if a plan’s provider network is inadequate to meet a beneficiary’s health care needs, the managed care organization must authorize the enrollee to obtain the needed care from out-of-network providers.67 For example, if a plan lacks a specialist qualified to treat an enrollee’s rare condition, the managed care organization must authorize the individual to go outside the plan to receive the necessary care. According to the Health Care Financing Administration, “a failure to authorize such care constitutes an adverse organization determination, with concomitant appeal rights.”68

Under the new rules, plans may now offer a point-of-service option as an additional or supplemental benefit for in-network as well as out-of-network services.69 The point-of-service option would enable enrollees to obtain health care services from contracting providers without following the plan’s prior authorization requirements. To prevent cost shifting to beneficiaries, however, the Health Care Financing Administration requires managed care organizations to track and report on point-of-service utilization by contracting and noncontracting providers to discern whether the plan is inappropriately denying prompt access to services from contracting providers.”70

2. Emergency and Urgently Needed Services

Managed care organizations bear financial responsibility for emergency or urgently needed services even if the services are obtained out of network or without prior authorization from the managed care organization. The new rules build upon and clarify the definitions and policies relating to emergency care, ambulance services, and urgently needed services.71 At the outset the final rule retains the prudent-layperson standard in defining emergency medical conditions. However, it adds new language that explicitly prohibits plans from retrospectively denying payment for services that were presented as emergencies under the layperson standard but which did not actually threaten the health of the patient.72

The definition of urgently needed services is changed in the final rule to

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65 Balanced Budget Refinement Act of 1999 § 502, 42 C.F.R. § 422.68(c). Previously elections made during open enrollment were effective the first day of the next calendar month.
66 42 C.F.R. § 422.101(a). Managed care organizations must maintain an accessible network of providers to offer basic benefits. 42 C.F.R. § 422.112. Moreover, if a plan provides additional benefits, mandatory supplemental benefits, or optional supplemental benefits, these must apply equally to all plan members. See 42 C.F.R. § 422.100(d), 422.102(a)–(b).
67 42 C.F.R. § 422.112(a)(3), 422.100.
69 42 C.F.R. § 422.105. The interim regulations restricted the point-of-service option to out-of-plan providers.
70 See id. § 422.105; 65 Fed. Reg. at 40210.
71 See 42 C.F.R. § 422.113.
72 See id. § 422.112(b)(2)(B)(iii). If the initial emergency room screening reveals that the patient’s condition is not actually an emergency, however, the managed care organization is not liable for postscreening services. In order to bill the beneficiary under these circumstances, the treating physician should provide an advanced beneficiary notice to inform the patient that the managed care organization would not cover further services. See 65 Fed. Reg. at 40203.
clarify that such services are not emergency services. Rather, they are non-emergency services provided when the enrollee is out of the service area or “(under unusual or extraordinary circumstances), provided when the enrollee is in the service or continuation area but the organization’s provider network is temporarily unavailable or inaccessible.” Such services must be medically necessary and immediately required as a result of an unforeseen illness, injury, or condition, and unreasonable to obtain from the managed care organization.73

The new regulations add provisions requiring managed care organizations to pay for ambulance services, including those dispatched through 911 or its local equivalent, “where other means of transportation would endanger the beneficiary’s health.”74 Managed care organization materials provided to enrollees (including wallet instructions) may not instruct enrollees to obtain prior authorization for emergency or urgently needed services, and marketing materials must affirmatively inform enrollees of their right to use 911 in emergencies.75 Similarly materials for providers may not require or instruct providers to seek prior authorization for services before the enrollee’s health has been stabilized.76 The Health Care Financing Administration retains the limit on copayments for emergency and urgently needed services obtained outside the plan’s network of the lesser of $50 or whatever the plan would charge for such in-plan care.”

3. Poststabilization Care Services

The new regulations clarify and add consumer protections to the interim regulations regarding poststabilization care services. In the Final Rule the Health Care Financing Administration clarifies that such care includes “covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under [certain] circumstances to improve or resolve the enrollee’s condition.”78

A managed care organization must pay for such services even if it did not preapprove them if the services are provided either (1) to maintain the beneficiary’s stabilized condition within the hour after the emergency provider contacted the managed care organization for authorization of further poststabilization care or (2) to “maintain, improve or resolve the enrollee’s stabilized condition” if (a) the managed care organization fails to respond to the emergency provider’s request for preapproval within one hour, (b) the managed care organization cannot be reached, or (c) the managed care organization representative and the treating physician disagree regarding the beneficiary’s care, and the managed care organization will not or cannot make a managed care organization physician available to consult with the treating physician.79 The rules add important protections for beneficiaries by specifying that the treating physician has the ultimate authority to decide when the

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73 42 C.F.R. § 422.113(b)(1)(iii). “Unusual or extraordinary” circumstances would include a strike or an earthquake. See 65 Fed. Reg. at 40199.
74 Id. § 422.113(a).
75 Id. § 422.113(b)(2)(A).
76 Id. § 422.113(b)(2)(B). The materials include provider contracts. Id.
77 Id. § 422.112(c)(2)(I).
78 Id. § 422.113(c)(1). The interim final rule included the requirement that managed care organizations cover “poststabilization care” provided to enrollees by contracting and noncontracting providers but did not clearly describe precisely what poststabilization care entailed.
79 The Health Care Financing Administration indicates that it may require emergency providers to seek plan authorization within the hour after the patient is stabilized for further services. The agency appears to believe that if the hospital fails to seek plan authorization for care within the hour after the patient is stabilized, the managed care organization may not be liable for further services. According to the agency, in such circumstances the provider may bill the patient only if a notice of noncoverage, such as an advanced beneficiary notice, has been given. See 65 Fed. Reg. at 40201–2.
enrollee may be considered stabilized for transfer or discharge and that the provider’s decision is binding on the managed care organization. 80

D. Grievances and Appeals

The new regulations add certain consumer protections to the Medicare + Choice appeals process but do not include additional grievance requirements. 81 The Health Care Financing Administration indicates that it plans to issue proposed regulations in the near future with additional improvements on the appeals process as well as new grievance procedures. 82

1. Expanded Definitions

At the outset the new rules expand the definition of authorized representative to recognize that such individuals include those “authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeals process.” 83 The revised definition thus clarifies that authorized representatives include decision-making surrogates under state law as well as individuals with a durable power of attorney. 84

The new rules include new examples of decisions that constitute organization determinations and are thus subject to appeal procedures. 85 First, decisions regarding payment for “temporarily [out-of-the-area] renal dialysis services” are not included with emergency services, post-stabilization care, or urgently needed care. 86 New language is also added to elucidate that a reduction in services triggers notice and appeal rights. 87 For exam-

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80 42 C.F.R. § 422.113(b)(3). See id. § 422.113(c)(3) for directives concerning managed care organizations’ financial responsibility for poststabilization care services.

81 Grievances are defined as any complaint or dispute that does not involve an organization determination. 42 C.F.R. § 422.561. Managed care organizations are required to offer “meaningful procedures” for hearing and resolving grievances. 42 C.F.R. § 422.564.


83 42 C.F.R. § 422.561 (emphasis added).

84 See 65 Fed. Reg. at 40283. The Health Care Financing Administration plans to address the issue of requiring additional protections (including additional notice requirements) for enrollees with special health care needs, including those who are disabled, chronically ill, or with diminished capacity in a future rule making. Id. Also, the regulations now eliminate the requirement that a physician requesting an expedited reconsideration for services be appointed as the enrollee’s authorized representative.

85 A managed care organization must develop appeal procedures for decisions regarding whether an individual “is entitled to receive health services under this section and the amount (if any) that the individual is required to pay with respect to such service.” 42 U.S.C. §§ 1852(g)(1)(A) & (B).

86 42 C.F.R. § 422.566(b)(1).

87 The Health Care Financing Administration will provide more specific guidance regarding when reductions in services represent organization determinations in a separate rule making. 65 Fed. Reg. at 40277.
ple, the rules specify that in general a managed care organization’s “refusal to provide or pay for services, in whole or in part, including the type or level of services” constitutes an organization determination. Similarly the rules clarify that a managed care organization’s decision to discontinue services is an organization determination whenever the enrollee believes that such services are medically necessary. However, a reduction or discontinuation of services activates the right to notice and appeal only if the enrollee disagrees with the managed care organization’s decision. The revised definition of organization determination indicates that a delay in the provision of services that would adversely affect the enrollee’s health may be appealed. The managed care organization’s failure to give timely notice of an organization determination may be appealed as well.

2. Time Frames

The new regulations make certain adjustments to the time frames set forth in the interim regulations for standard and expedited organization determinations and reconsiderations. Managed care organizations must now follow the same 72-hour period for expedited organization determinations and reconsiderations, whether or not a noncontract provider or plan provider is involved. The managed care organization must now “request the necessary information from the non-contracting provider within 24 hours of the initial request for an expedited organization determination” or an expedited reconsideration.

The new regulations also now require that, whenever a managed care organization extends the time frame for a decision, it must give the enrollee a written notice of the reasons for the extension and of the right to file a grievance if the enrollee disagrees with the managed care organization’s delay. If the managed care organization denies the request for an expedited determination or reconsideration, the organization must now give the enrollee “prompt oral notice of the denial” and deliver within 30 calendar days a written notice that (1) informs the enrollee of the right to resubmit the request for expedite with a physician’s supporting opinion and (2) offers instructions about filing a grievance to contest the denial to expedite the decision.

The new regulations shorten the period within which managed care organizations must pay for, authorize, or provide services following appeal decisions that are favorable to the enrollee. For example, for standard service-related requests, if the independent outside agency reverses the managed care organization’s decision in whole or in part, the organization

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88 42 C.F.R. 422.566(b)(3). The Health Care Financing Administration explains that, while many decisions to deny or to discontinue services involve medical necessity determinations, others may entail only how limitations on benefits (including additional and supplemental) apply to a given set of facts. See 65 Fed. Reg. at 40277.
89 42 C.F.R. 422.566(b)(4). See also 65 Fed. Reg. at 40277.
90 This proviso represents a loophole in the regulations. However, a new provider notice requirement may mitigate this problem somewhat. At “every patient encounter” a provider must give the enrollee a written notice of the right to request and receive a “detailed” notice from the managed care organization regarding the decision made by the practitioner or the organization to “deny or reduce services, in whole or in part.” The notice must include information needed to contact the organization and satisfy standards set by the Health Care Financing Administration. Id. § 422.568(c)-(e). The agency plans to develop a standardized provider notice through the Office of Management and Budget Paperwork Reduction Act process. 65 Fed. Reg. at 40278.
91 42 C.F.R. 422.566(b)(5). See also id. § 422.561 (revised definition of appeal).
92 Id. § 422.568(f).
93 See id. § 422.572, 422.590(d)(4). The interim rule had provided that the 72-hour time period did not begin until the managed care organization received required information from the noncontracting provider.
94 Id.
95 Id. § 422.568(a); 422.572(b).
96 Id. § 422.584(d).
must now “authorize the service under dispute within 72 hours from the date it receives the notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee’s health condition requires, but no later than 14 calendar days from that date.” Further, for independent entity reversals of decisions denying expedited requests for services, a managed care organization “must authorize or provide the service under dispute as expeditiously as the enrollee’s health requires, but no later than 72 hours after the [managed care organization] receives the request for reconsideration or the [organization] receives notice from the independent entity reversing the determination.”

3. Noncoverage of Inpatient Hospital Care

Under the new rules, whenever a decision is made to discharge an enrollee from the hospital, whether or not the beneficiary indicates disagreement, written notice must be given to the enrollee no later than the day before the planned discharge. The notice must contain (1) the reason hospitalization is no longer required, (2) the effective date and time of the enrollee’s liability for continued inpatient care, (3) the enrollee’s appeal rights, and (4) additional information specified by the Health Care Financing Administration.

The new regulations shift the responsibility for distributing discharge notices to Medicare+Choice enrollees from managed care organizations to hospitals. Nevertheless, the plan must still make itself available for enrollee questions about its discharge decisions.

E. New Private Fee-for-Service Plan

The Sterling Life Insurance Company has launched the first Medicare+Choice private fee-for-service plan. Sterling Option I, to operate in selected areas. Private fee-for-service plans receive set monthly payments from Medicare to arrange for health care coverage for Medicare beneficiaries who have enrolled. The plans reimburse doctors, hospitals, and other providers on a fee-for-service basis at a rate determined by the plan rather than the Medicare rate. Private fee-for-service plans may not put the provider at risk or vary rates based on the provider’s utilization of services.

Enrollees in private fee-for-service plans are not restricted to a network of providers, nor are they required to obtain referrals from primary care providers before seeing specialists. They may...
visit any doctor or hospital that is willing to provide care and to accept the private fee-for-service plan’s terms and conditions of payment.\textsuperscript{105} Private fee-for-service plans must have a sufficient number and range of providers to satisfy standards governing access to care.\textsuperscript{106}

Enrollees in Medicare+Choice private fee-for-service plans must continue to pay their monthly Medicare Part B premiums, as well as the private fee-for-service plan premium and any deductible or cost-sharing amounts required by the plan. Medicare+Choice private fee-for-service plans may also permit contracting providers to balance-bill beneficiaries for up to 15 percent of the private fee-for-service payment rate for the service, in addition to the cost-sharing amount required by the plan.\textsuperscript{107} However, noncontracting providers may not balance-bill beneficiaries and must charge no more than the cost sharing allowed under the plan.\textsuperscript{108}

Furthermore, private fee-for-service plans are exempt from quality assurance requirements that govern most other Medicare+Choice plans.\textsuperscript{109} In contrast to traditional fee-for-service Medicare providers, Medicare+Choice private fee-for-service providers need not give advance beneficiary notices if they believe that Medicare may not cover a particular service. However, private fee-for-service plans must supply, if requested by the beneficiary, a determination of coverage before the beneficiary receives the service; that determination is binding on the plan.\textsuperscript{110}

While private fee-for-service plans may be a good option for some, they are not appropriate for all beneficiaries.\textsuperscript{111}

\textbf{While private fee-for-service plans may be a good option for some, they are not appropriate for all beneficiaries.}

For that reason, before joining a plan, beneficiaries should take the following into consideration: (1) the out-of-pocket expenses entailed (including balance billing); (2) the extent to which additional benefits, such as prescription drugs, are

\textsuperscript{105}A managed care organization must treat a provider without a written contract with the plan as a “deemed” contract provider if the provider knew that the individual was a plan enrollee (e.g., through presentation of the enrollment card) and either was aware of the plan’s terms and conditions or had reasonable opportunity to learn those terms and conditions (e.g., through plan Web site or mailing). See 42 C.F.R. \textsuperscript{106} 422.216(f); 66 Fed. Reg. at 40297.

\textsuperscript{106}42 C.F.R. § 422.114. According to the Health Care Financing Administration, a managed care organization meets access requirements for a specific category of provider if it has (1) payment rates that are no less than the provider in question would have been paid under traditional fee-for-service Medicare, (2) a sufficient number of written contracts with providers, or (3) a combination of both. See 66 Fed. Reg. at 40296. Providers without an opportunity to learn of a beneficiary’s enrollment in a plan (e.g., through enrollee membership card or plan Web site and mailings) are considered “noncontracting providers.” The new regulations clarify that providers or hospitals that provide services to enrollees in emergency departments under the Emergency Medical Treatment and Active Labor Act may not be deemed contracting providers. 42 C.F.R. § 422.216(f).

\textsuperscript{107}Hospitals are required to give beneficiaries advance notice if their financial liability will exceed $500 or more, but no such notice is required from other providers. See 42 C.F.R. § 422.216(d)(2); 66 Fed. Reg. at 40294.


\textsuperscript{111}Beneficiaries who might wish to consider a private fee-for-service plan would include, e.g., those who travel extensively in the continental United States, who live in areas not served by other Medicare+Choice plans, or who wish to see specialists directly without referrals.
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offered,\textsuperscript{112} (3) prior-authorization requirements for services; and (4) the likelihood that the enrollee’s provider of choice or a sufficient number of providers will participate in the plan.

The Medicare developments discussed here affect beneficiary access to reasonably necessary and quality health care. Advocates for beneficiaries face the challenge of keeping pace with these changes and of monitoring their implementation to ensure the protection of beneficiary rights in the delivery and receipt of Medicare-covered services.

\textsuperscript{112} See Private Fee-for-Service Plans Questions and Answers <www.hcfa.gov> for more information.