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BEHAVIORAL HEALTH ISSUE BRIEF SERIES

Issue Brief #1¹

Coverage Decision-Making in Medicaid Managed Care: Key Issues in Developing Managed Care Contracts

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Executive Summary

Coverage provisions are the most complex part of any managed care contract. This is particularly true for Medicaid agencies, because of important differences between Medicaid and insurance. This Issue Brief identifies general issues that should be addressed as managed care contracts are developed and drafted, and it specifically explores the challenges faced by public purchasers when drafting managed care coverage provisions.

Introduction

A central issue in any contract of insurance (including managed care contracts)² is the provisions that govern how coverage will be determined. Coverage determination entails a series of sub-issues: how coverage will be decided and by whom; the standards that will be used to determine coverage; the exclusions from coverage that will be permitted under the contract; the process for reviewing coverage determinations; and the remedies that will be available for erroneous determinations.

Coverage decision-making has been a central matter in insurance policy for decades. However, it has received far greater attention in recent years with the advent of managed

¹ A sample of the types of topics the Issue Brief Series might cover in the future include: Quality in Managed Care Contracting; Out-of-Plan Care (including a discussion of court- and agency-ordered treatment); Contract Compliance and Monitoring (including a discussion of issues related to contract start-up and oversight in a contract's first year of existence); Network Formation and Adequacy; Benefits versus Defined Contributions; and Issues in the Development of Carve-Out Contracts.

² In this Issue Brief, the term "insurance coverage" is used to denote any type of health plan (including an employer-based plan) that uses traditional insurance principles to make coverage determinations. In their coverage decision-making role, managed care organizations (including HMOs) have the features of insurance carriers and may be licensed as such in some states. See, e.g., *McEvoy v Group Health Cooperative of Eau Claire*, 570 N.W.2d 397 (Wis. Sup. Ct. 1997).

care and the growth of *prospective* coverage determination procedures.³ Prospective decision-making has been a common insurance practice for more than 20 years, but its frequency has grown under managed care in order to achieve greater control over health care budgeting and the allocation of health services themselves. As a result, Americans have become far more sensitive to the issue of coverage decision-making, because coverage increasingly is equated with access. In recent years, many state lawmakers have sought to address aspects of coverage decision-making, and numerous bills that would affect all aspects of coverage decision-making now are pending in Congress.

This Issue Brief examines the elements of coverage decision-making and considers their implications for Medicaid managed care contracting. While this Issue Brief focuses on Medicaid, its discussion is potentially applicable to other forms of publicly purchased insurance coverage (such as managed care enrollments purchased with Community Mental Health Services Block Grant funding⁴). This is because, like Medicaid, other forms of public health care financing frequently have covered care and services that fall outside traditional notions of what is insurable. If these differences are not taken into account as contracts are developed, the result can be the unintended loss of certain aspects of coverage, especially for individuals with serious and chronic illness whose health care needs fall outside of traditional insurance norms. In the case of Medicaid, which is governed by a complex federal statute with its own coverage standards, state agencies remain liable for coverage of all Medicaid benefits, regardless of whether they contract with private risk companies to help administer a portion of their state plans. Other public health care financing programs are unlike Medicaid in that they are not structured as defined-benefit entitlement programs. Nonetheless, depending on their scope of coverage under state law, these other programs may either retain residual liability for coverage or else experience the loss of certain coverage as a result of their differences from traditional insurance.

Distinguishing Between Medicaid and Insurance Principles

It is easy to think of Medicaid as public insurance. Indeed, national statistical estimates of insurance coverage patterns among Americans treat Medicaid as public insurance. To be sure, Medicaid has the essential features of insurance: It is a program that entitles eligible persons to coverage for a defined set of health care items and services, many of which are also found in traditional insurance policies. In both Medicaid and insurance, moreover, coverage of enumerated items and services is limited to care that is medically necessary.

At this point, however, the similarities between Medicaid and private insurance cease in certain key respects. Medicaid is a public, third-party financing program that entitles eligible persons to a benefit package defined by federal statutes and regulations. This benefit package finances a broader range of health care than typically is available through insurance, because Medicaid beneficiaries generally are in poorer health than persons covered by private insurance.⁵ Actual coverage of enumerated benefits is governed

³ See Rand Rosenblatt, Sylvia Law, and Sara Rosenbaum, *Law and the American Health Care System* (Foundation Press, Old Westbury N.Y., 1997; 1998 Supplement), Ch. 2(E).

⁴ See 42 U.S.C. §§300x—300x-35.

⁵ This is true not only in the case of elderly and disabled persons, but also with respect to families with children. See, e.g., W. Pete Welch and Martia Wade, “Relative Costs of Medicaid Enrollees and the

by tests of reasonableness.⁶ On the other hand, traditional insurance is designed to cover an essentially healthy work force and operates in accordance with contractual principles of coverage. And while virtually all states mandate the inclusion of certain benefits in state-regulated insurance policies and federal lawmakers in recent years have demonstrated a growing interest in mandated benefits, the actual determination of coverage for any enumerated class of benefits is governed by the contracts of coverage between buyers and sellers, which rest upon the principles of the insurance industry itself. These principles can be quite different from those which govern Medicaid, and they must be kept in mind when developing Medicaid managed care service agreements.

Medicaid/Insurance Distinctions

Some of the distinctions between Medicaid and private insurance are relatively well known. As noted, Medicaid covers many classes of benefits that are not commonly found in private insurance, such as long-term hospitalization for physical and mental health problems and nursing home and home health benefits without regard to prior hospitalization status.⁷ Medicaid benefits also must be covered without arbitrary limits on the amount or duration of coverage; this is especially true for children.⁸ For example, Medicaid-enrolled children with mental illness are entitled to all medically necessary care, while privately insured children may be covered for only a certain number of outpatient visits each year. Another distinction can be found in the definitions used to describe covered items and services. For example, Medicaid's statutory definition of pregnancy-related care includes not only prenatal, delivery, and post-partum care but, unlike insurance, also care for conditions that could complicate pregnancy.⁹

Other distinctions between Medicaid and private insurance are more subtle and are evident only through careful comparison of Medicaid and private insurance principles. These differences become evident during individual coverage determinations (i.e., the process by which the payor decides if an enrollee is eligible to have benefit payments made on his or her behalf).

The "restore to normalcy" test. One subtle but key distinction between insurance and Medicaid is how the two systems address the coverage needs of persons with chronic illness. The principal goal of insurance is to cover workers and their families; thus, coverage may

Commercially Insured in HMOs," *Health Affairs* 14:2, pp. 212-24 (Summer, 1995); Pamela Loprest and Gregory Acs, "Profile of Disability Among Families on AFDC," The Urban Institute (August, 1996).

⁶ 42 C.F.R. §440.230(c). See, e.g., *Curtis v Taylor*, 625 F. 2d 645 (5th Cir. 1980); *Beal v Doe*, 432 U.S. 438 (1979); *Alexander v Choate*, 469 U.S. 287 (1985). Special tests of reasonableness apply to Medicaid coverage of children under 21 because of the preventive nature of the program. *Bond v Stanton*, 655 F. 2d 766 (7th Cir. 1981); *Mitchell v Johnston*, 701 F. 2d 337 (5th Cir. 1983).

⁷ 42 U.S.C. §§1396d(a)(1) and (2).

⁸ See *Curtis v Taylor* and *Alexander v Choate*, *supra* note 6. Limits can be placed on the amount, scope, or duration of coverage as long as the needs of the overwhelming majority of patients are satisfied. In the case of children, courts have consistently overturned limitations in coverage that might have been acceptable in the case of adults because of the preventive purposes of Medicaid's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefit package, to which all children under age 21 are entitled. For a review of EPSDT litigation, please request from the Center for Health Policy Research a copy of *An Overview of EPSDT Administrative and Coverage Cases*, prepared by Sara Rosenbaum, Joel Teitelbaum, and Colleen Sonosky.

⁹ 42 U.S.C. §1396a(a)(10)(E).

be limited to care and services that are necessary to permit an acutely sick person to recover to a prior normal functioning level. Care and services needed to maintain a chronically ill person in relatively stable health might be excluded as not necessary for recovery.

The “illness or injury” test. Another distinction has to do with the scope of health problems covered by private insurance and Medicaid. Medicaid covers services needed to treat not only “illnesses and injuries”, but also undefined conditions--such as developmental disabilities in children--that do not stem from an acute illness or injury. Limitations that exclude treatment for such conditions possibly would be permissible under traditional insurance,¹⁰ but not under Medicaid.¹¹ For example, a toddler who needs speech therapy to ameliorate the effects of a developmental disability would be eligible for coverage under Medicaid but not under an insurance plan that limited speech therapy coverage to individuals recovering from an illness or injury (e.g., a stroke).

Exclusions and evidence. An additional distinction between Medicaid and insurance involves the use of exclusions. As noted, both Medicaid and insurance coverage exclude coverage of services that are not medically necessary. But insurers typically employ many more exclusions and may use broader measures to determine when something is excluded. For example, covered services furnished to children who need special education and related medical care under the Individuals with Disabilities Education Act may be excluded by insurers as “educational”. However, this exclusion is expressly prohibited under Medicaid.¹² Additionally, a growing number of insurers may elect to exclude services that do not comport with industry-developed practice guidelines or that have not been proven effective through controlled, randomized trials. Such exclusions may be lawful if the insurance contract does not expressly provide for such coverage or if the decision to exclude is not an abuse of discretion.¹³ Medicaid principles, on the other hand, require Medicaid agencies to use reasonable, non-discriminatory criteria in setting exclusions and limitations. For example, where a procedure is accepted among relevant health practitioners and there is no contradictory body of evidence from scientific studies to indicate its non-effectiveness, coverage must be permitted.¹⁴ Thus, insurance principles give insurers broad discretion to set the parameters of coverage in the absence of express contractual provisions requiring coverage. The discretion of Medicaid agencies, on the other hand, is bound by tests of reasonableness.

Procedural due process distinctions. A final distinction has to do with the process for determining coverage and the procedures that must be followed when coverage is denied, reduced, or terminated. Medicaid policy limits the use of prior authorization programs,

¹⁰ The impact of the Americans with Disabilities Act on such distinctions has not yet been tested. It is possible that such coverage distinctions based on a member’s condition are no longer lawful. For a broader discussion of this issue, see *Law and the American Health Care System*, *supra* note 3, Chs. 2(F) and 4. For an example of the distinction between illnesses and injuries on the one hand and conditions on the other, see “Calling Infertility a Disease, Couples Battle With Insurers,” Esther B. Fein, *The New York Times*, February 22, 1998, Section 1, Page 1.

¹¹ 42 C.F.R. §440.230(c) prohibits arbitrary limitations on required services based on a beneficiary’s diagnosis or condition. See, e.g., *Beal v Doe*, *supra* note 6.

¹² 42 U.S.C. §1396b(e).

¹³ See, e.g., *Adams v Blue Cross and Blue Shield of Maryland*, 757 F. Supp. 661 (D. Md. 1992).

¹⁴ See, e.g., *Weaver v Reagen*, 701 F. Supp. 717 (D. Mo. 1988); *Rush v Parham*, 440 F. Supp. 383 (D. Ga. 1977).

particularly in the area of drug coverage.¹⁵ Additionally, prior authorization systems must function reasonably, taking into account the scope and speed of review, the review standards, and the evidence that reviewers must consider.¹⁶ In the case of prescribed drugs, states that use drug formularies must abide by certain prior authorization procedures and must provide immediate supplies of non-formulary drugs when an emergency medical need presents itself. Conversely, private insurers have broad latitude to fashion prior authorization programs in the absence of express contractual provisions.¹⁷

Moreover, because Medicaid is a need-based welfare program, constitutional principles of due process prohibit individual, fact-based coverage denials, reductions, or terminations from becoming final until an individual has been afforded an opportunity for an impartial, fair hearing.¹⁸ When the reduction or termination of assistance is involved, the decision of the agency cannot take effect until a fair hearing has been conducted, if a timely request for a hearing is made.¹⁹ Under Medicaid, the burden of proof falls to the agency to show why coverage should not be provided. An insurer's coverage decisions, on the other hand, take effect immediately, and the burden is on the claimant to show that the insurer's determination violates the terms of the contract or principles of tort law.²⁰

Implications of Medicaid/Insurance Distinctions for Contract Drafting

A state Medicaid agency, in contracting with managed care insurers, may decide to buy the insurer's traditional product and continue to provide direct coverage for those items and services that are excluded by the insurer. The agency may also decide to retain direct responsibility for procedural reviews, including prior authorization reviews and the evidentiary phase of a fair hearing process. The agency can also decide that it will pay for items and services that fall outside the scope of the agreement as a result of the insurer's use of coverage determination procedures that differ from those applicable to Medicaid. But most agencies desire to buy precisely these coverage determination and review services from their managed care contractors. Where contracts fail to track the law, the results can be unexpected liability on the part of the agency for Medicaid services and procedures that fall outside the contract but within the scope of Medicaid,²¹ as well as confusion and *de facto* loss of coverage and protections for beneficiaries. These oversights can also place burdens on managed care companies, who may not understand these key distinctions and who face sanctions by the Medicaid agency for the denial of covered care.

For these reasons, care is needed in developing the coverage components of a managed care service agreement. The Balanced Budget Act of 1997 heightens the need for

¹⁵ 42 U.S.C. §1396r—8(d)(5).

¹⁶ See, e.g., *Dodson v Parham*, 427 F. Supp. 97 (N.D. Ga. 1977); *Wickline v State of California*, 741 P. 2d 613 (Cal. 1987).

¹⁷ This discretion is subject to certain limitations such as a breach of contract claim or a tort liability claim, particularly the tort of bad faith breach of contract. See, e.g., *McEvoy v Group Health Cooperative of Eau Claire*, *supra* note 2.

¹⁸ 42 U.S.C. §1396a(a)(4); 42 C.F.R. §431.231(a)(3).

¹⁹ 42 C.F.R. §431.231(c).

²⁰ See, e.g., cases cited in Law and the American Health Care System, *supra* note 3, Ch. 2(E).

²¹ Regardless of whether state agencies administer their Medicaid programs directly or through insurance contractors, they remain liable for compliance with federal law, and this obligation is non-delegable. See, e.g., *J.K. v Dillenberg*, 836 F. Supp. 694 (D. Az. 1993); *Daniels v Wadley*, 926 F. Supp. 1305 (D. Tenn. 1996).

attention to this set of issues: The Act requires state agencies and managed care organizations to fully disclose to beneficiaries which Medicaid services are available through the managed care plan and which will continue to be furnished directly by the state agency. Specifically, the Act provides that each managed care contract “shall specify the benefits and the provision (or the arrangement) for which the entity is responsible.”²²

As this Issue Brief demonstrates, drawing a managed care contract’s coverage line is far more complex than merely identifying which *classes* of benefits are covered in the contract; for even within a covered class of benefits, some services may be in the agreement itself while others may fall outside the scope of the contract and remain directly covered.

Key Issues in Contract Development and Drafting

In light of the above discussion, agencies and plans should consider the following issues when developing contracts and establishing premiums.

1. The Medical Necessity Standard²³

Agencies should articulate a medical necessity standard that conforms to their current standard and that incorporates into the definition provisions related to evidence and burdens of proof. Thus, for example, agencies should consider specifying that coverage is to be measured in accordance with accepted standards of medical and health practice and can be denied, reduced, or terminated only if the insurer can demonstrate that the proposed coverage is contrary to the opinions of relevant practitioners who have expertise in the field or specific and to relevant scientific studies. This type of clause maintains a “professional” standard (as opposed to an “evidence-based” or “corporate” standard) for decision-making and ensures that adverse coverage determinations are based on reasonable evidence and that the burden of proof remains with the decision-maker.

In the case of coverage for children, coverage must occur at a point at which treatment can *prevent or ameliorate* an illness or condition. Pennsylvania’s 1996 Request For Proposal contains a comprehensive definition of pediatric medical necessity:

[For a service to be medically necessary, one of the following standards must be met:]

The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability[;] The service or benefit will, or is

²² 42 U.S.C. §1396v(b)(1). The statute also provides that “A State directly or through managed care entities shall, on or before an individual enrolls with such an entity * * * inform the enrollee in a written and prominent manner of any benefits to which the enrollee may be entitled to [sic] under [Medicaid] but which are not made available to the enrollee through the entity. Such information shall include information on where and how such enrollees may access benefits not made available to the enrollee through the entity.”

²³ For other discussions regarding the importance of medical necessity standards in coverage decision-making, see “Defining ‘Medically Necessary’ Services to Protect Plan Members,” Managed Mental Health Care Policy #1, The Bazelon Center for Mental Health Law (Washington, D.C. 1997), and “Contracting for Managed Substance Abuse and Mental Health Services: A Guide for Public Purchasers,” Technical Assistance Publication Series, Health Systems Research, Inc. (Washington, D.C., December, 1997).

reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability[;] The service or benefit will assist the individual to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age. Pennsylvania RFP (Rosenbaum et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts (1st Ed.)*, Vol. II(1), p. 2-584) (The George Washington University Medical Center, Washington, D.C. 1997)

At least one state has expressly elected to depart from the coverage, evidentiary, and burden-of-proof standards that traditionally have governed Medicaid. Nebraska's Medicaid managed care contracts specifically incorporate a coverage provision that is consistent with emerging insurance principles of "evidence-based" medical necessity, principles that permit insurers to limit the evidence they will consider to industry-developed practice standards and the results of randomized clinical trials (which for many reasons are still extremely rare).²⁴ Moreover, the Nebraska definition places the burden of proof on the claimant, rather than on the company. The state's contract provides that:

The term "medical necessity" and "medically necessary" with reference to a covered service means health care services and supplies which are medically appropriate and * * * (3) *consistent in type, frequency and duration of treatment with scientifically based guidelines or national medical, research or health coverage organizations or governmental agencies*; * * * (7) *of demonstrated value*; * * *. The fact that the physician has performed or prescribed a procedure or treatment or the fact that it may be the only treatment for a particular injury, sickness or mental illness does not mean that it is medically necessary. Nebraska Mental Health Contract (Rosenbaum et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts (1st Ed.)*, Vol. II(1), p. 2-282) (The George Washington University Medical Center, Washington, D.C., 1997) [Emphasis added.]

The legality of this evidentiary standard has not yet been tested in Medicaid law. To the extent that an agency follows the standard, it may want to retain the authority, as discussed above, to override specific coverage decisions under the test.

2. Permissible Exclusions and Definitions

Contracts should address in detail the applicability of certain common insurance exclusions, including the exclusion of experimental services as well as the exclusion of services solely because of the manner or setting in which they are furnished or the basis of the coverage request. Common insurer exclusionary practices can be found in the areas of "educational" services, "social" services (e.g., services recommended by child welfare agencies), court-ordered treatment, or treatment identified as necessary by, for example, an

²⁴ For an excellent article setting forth the elements of evidence-based necessity, see David M. Eddy, *Rationing Resources While Improving Quality: How to Get More for Less*, 272 JAMA 817 (1994).

education agency or other agency caring for a managed care enrollee. Many of these services now are covered by states as a matter of either mandatory or discretionary policy.

Definitions also are important. As the “pregnancy-related care” example above indicates, in a number of instances Medicaid uses relatively broad federal or state plan definitions to delineate the scope of a covered service. Agencies should consult applicable statutes and regulations to ensure that their contract definitions are consistent with federal and state law. In the case of state plan definitions, agencies should determine if they will hold their contractors to the state plan scope of coverage or allow companies to alter or narrow the terms of coverage, thereby creating residual agency liability as a matter of state law.

3. Prior Authorization Systems and Procedural Due Process

Some, but not all, state managed care service agreements currently in force delineate basic rules for prior authorization programs, including prior authorization statutory mandates. At a minimum, the federal drug coverage provisions should be incorporated by reference and states should consider developing general standards that specify reasonable time frames for coverage determinations, with automatic approval in the event that an insurer’s timelines do not prove to be reasonable. Key general issues are: (1) the appropriateness of prior authorization at all (e.g., prohibiting its use in emergency situations); (2) time lines for determinations (e.g., within one day of the request in the case of urgent care, or within eight hours of a request for an off-formulary drug); (3) the qualifications of reviewing personnel (e.g., determinations of medical necessity of extended addiction treatment services may be made only by a professional with expertise in addiction treatment); and (4) the form and time lines for communicating the decision (e.g., a written decision within one day of the determination, communicated to the provider and the beneficiary).

With respect to the review of coverage determinations, most Medicaid contracts require grievance and appeal systems for beneficiaries who are denied coverage; the Balanced Budget Act of 1997 mandates the use of such systems in states that elect to purchase Medicaid managed care as a state option. However, many contracts do not set forth procedural specifications for grievances, even though the managed care grievance process, if properly constructed, could theoretically function as the initial evidentiary determination phase of the federal fair hearing process, thereby bringing the two systems into closer accord. To address this issue, states should specify in their contracts that: (1) contractor actions that constitute an adverse determination under the fair hearing system also are grievable; (2) plan notices must comport with federal content and form requirements; (3) where a grievance is requested in a timely fashion, coverage must continue pending the final fair hearing decision; (4) the grievance itself should comply with all regulatory requirements regarding local evidentiary hearings; and (5) individuals can appeal an adverse grievance decision to the state.

²⁵ See Sara Rosenbaum et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts (2d Ed.)* (The George Washington University Medical Center, Washington, D.C., 1998).

²⁶ 42 U.S.C. §1396v(b)(4).

4. Reserving State Authority to Clarify Contract Coverage

Even when care is taken to conform Medicaid and general managed care contract coverage policies, there may be lapses or gaps where none was anticipated. An agency may want to consider following the lead of several states which incorporate into contracts provisions authorizing the state to rule on initial coverage determinations. This authority may be particularly important for services commonly used by persons with chronic illness or for services furnished in alternative settings (such as special education-related medical care) where traditional notions of insurance may result in higher than expected exclusions. Such authority may also be important for services ordered by courts or other public agencies, where the state Medicaid agency may want to evaluate the basis of the insurer's denial.

Measuring Performance as it Relates to Medical Necessity Issues

An essential part of any contract is an explanation of how performance on a particular specification will be measured and the information that the purchaser requires of the health plan. Performance measurement standards are particularly important in public contracts, because due process considerations require clarity in compliance measurement. Performance measurement--including both internal quality performance assessment and external review--regarding medical necessity determinations requires a combination of structure, process, and outcomes measures, examples of which follow:

Structure measures: all written materials furnished to network providers regarding coverage, applicable limitations and exclusions, an explanation of how medical necessity determinations will be made, and identification of services and procedures that require prior authorization;

Process measures: explanation of how medical necessity determinations are carried out (e.g., timelines for determinations, qualifications of personnel making determinations, and descriptions of evidence considered and the protocols used), description of the prior authorization program, copies of all practice guidelines used, forms for submission of evidence, and sample forms used to explain coverage decisions;

Outcomes measures: the results of reviews of individual medical necessity determinations for selected services chosen by the purchaser, with ratios of approvals and denials to requests for prior authorization.

²⁷ The right to a fair hearing regarding coverage of contract services means that, in effect, all insurer coverage determinations are subject to state review. Authorizing state intervention at an earlier point in the determination process may be more efficient.

²⁸ An example of such an authorizing provision is, "The agency reserves the right (i) to review Contractor's coverage determinations with respect to the services and items enumerated under this contract; and (ii) to require the Contractor to provide coverage in those instances in which the state deems coverage to be medically necessary."

Conclusion

Addressing coverage issues in Medicaid is a challenge; however, the underlying structure of Medicaid demands rigorous attention by state agencies because of the potential loss of benefits among enrollees and unanticipated financial exposure among states. In managed care contracting, clear policy decisions and careful drafting are essential because of the coverage and financial implications of error. Therefore, the added time spent on coverage matters represents a pivotal investment for state agencies, particularly as they move an increasingly disabled population into managed care. Moreover, even where a contract is well-drafted, follow-up monitoring is vital. Monitoring schemes should consider a contractor's medical necessity review structure (e.g., instructions to providers and the professional experience of the contractor's reviewers); review process (e.g., logs showing the date on which a request was made and the date on which a decision was communicated in writing, or time line data for resolution of expedited appeals); and review outcomes, particularly for services and procedures required by persons with chronic illnesses or furnished in special settings.