achieved, and any confounding factors that might influence the evaluation results achieved through the delivery of such services. For illustrative purposes, below are examples of some of the types of information that could be required to carry out an evaluation, and for which the evaluator would need patient level identifiers.

- Utilization data not otherwise available through existing Center for Medicare & Medicaid Services (CMS) systems.
- Beneficiary, patient, participant, family, and provider experiences.
- Beneficiary, patient, participant, and provider rosters with identifiers that allow linkages across time and datasets.
- Beneficiary, patient, participant, and family socio-demographic and ethnic characteristics.
- Care management details, such as details regarding the provision of services, payments or goods to beneficiaries, patients, participants, families, or other providers.
- Beneficiary, patient, and participant functional status and assessment data.
- Beneficiary, patient, and participant health behaviors.
- Clinical data, such as, but not limited to lab values and information from EHRs.
- Beneficiary, patient, participant quality data not otherwise available through claims.
- Other data relevant to identified outcomes—for example, participant employment status, participant educational degrees pursued/achieved, and income.

We invite public comment on this proposal to mandate the production of the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act.

In addition, we are proposing a new subpart K in part 403 to implement section 1115A of the Act.

F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

1. Background

On April 1, 2014, the PAMA was enacted and section 216 addresses Medicare payment and coverage policies for clinical diagnostic laboratory testing. In regard to coverage policies, section 216 amended the statute by adding section 1834A(g) of the Act, which establishes mandates related to issuance of local coverage policies by the Medicare Administrative Contractors (MACs) for clinical diagnostic laboratory tests. The law states: ''A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1869(f)(2)(B)), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).''

Section 1869(f)(2)(B) of the Act defines a local coverage determination (LCD) as ''a determination by a fiscal intermediary or a carrier under Part A or Part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A) of the Act.''

Since the new law requires that the process for making local coverage determinations be used as the vehicle for local coverage policies for clinical diagnostic laboratory tests, it is important that we carefully consider the LCD process that is used today and determine if there are certain, limited aspects of the LCD process that may provide an opportunity to better fit the needs of this particular area of medicine. In addition to the current LCD process, we will examine how the LCD process was applied to a pilot project for molecular diagnostic tests as we are learning important lessons from this ongoing pilot. We believe lessons learned from this project can be applied to all clinical diagnostic laboratory testing and not just molecular diagnostic tests (which are encompassed under the PAMA requirement for local coverage policies). In this proposed process, we will review the current LCD process, as well as the pilot in support of a proposal to create, consistent with the requirements set forth under the PAMA, an expedited LCD process for clinical diagnostic laboratory testing.

The current LCD process (Table 18) requires that a draft LCD be published in the Medicare Coverage Database (MCD). This serves as a public announcement that an LCD is being developed. Once a draft LCD is published, at least 45 calendar days are provided for public comment. We note that the National Coverage Determination (NCD) process only requires a 30-day public comment period after a proposed NCD is published. This timeframe is based on the NCD statutory requirements under 1862(l) of the Act and in our experience at the national policy level, 30 days is generally adequate to allow for robust public comment.

After the draft LCD is made public, MACs are required to hold an open meeting to discuss the draft LCD with stakeholders. In addition to the open meeting, the MACs present the draft policy to the Carrier Advisory Committee (CAC). These two aspects of LCD development can be time-consuming and may involve logistical complications that extend the length of time it takes to reach a final policy. We note that unlike the national advisory committee, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), the CAC meetings and open stakeholder meetings are scheduled to discuss many LCD policies at a time as opposed to narrowly focusing on one policy. Due to the resources required, the constant development of LCDs and scheduling considerations, MACs do not hold ad hoc meetings. Both the open stakeholder meetings and the CAC meetings are scheduled far in advance, generally at the start of the calendar year before MACs know which policies will be presented in these forums. The timing of the open stakeholder meeting, CAC meeting, and public release of the draft LCD are all factors in determining which LCDs are on the agendas. Because of these scheduling issues, some LCDs may not have to wait as long for a CAC meeting or an open stakeholder meeting while others could have lengthy delays. In contrast, at the national level, MEDCACs are not convened for every NCD and separate open meetings are also not a part of the NCD process. Based on our experience with the NCD process over the past decade, we believe that public input is now readily available through more technologically advanced mechanisms of collecting public comment. For example, the information gathered and knowledge gained from the LCD open stakeholder meetings may now be acquired more broadly through the collection of public comments via web-based applications. CMS and its contractors are receiving more input on their policies because of these technology advances, which were not as available to the public when the LCD manual was originally written approximately 25 years ago. Medical literature, clinical practice guidelines, complicated charts and graphs can now be easily submitted electronically through the public comment process. Questions or follow-up information from a specific commenter can be addressed through conference calls or email. In addition, through these processes, all public comments are available to everyone rather than to the few people who attend meetings in

person. In addition to publishing a draft LCD, MACs publish a document that provides a summary of all of the comments received and responses to those comments. This allows the public to understand the reasoning behind the final LCD and to know that all of the public comments were taken under consideration as the MAC developed the final policy. Since this information is made readily available in writing, an open meeting is no longer necessary for the public to be heard. There are more efficient methods available to the public to submit comments and additional evidence that supports or rejects the application of a draft LCD.

Somewhat different considerations apply to CACs, which are state-specific bodies representing the clinical expertise of a geographic area. CACs allow a unique opportunity for CAC members to provide practical information regarding a draft policy since they are the entities actually delivering services in the community. However, like MEDCACs, a CAC may not be needed in all instances for the creation or revision of an LCD. CAC meeting agendas can quickly fill up with draft LCDs since the CAC meetings are scheduled far in advance. We believe CACs may be a better resource and used more efficiently in the development of LCDs if the MAC is able to select which draft LCDs are presented to a CAC for discussion, as opposed to taking all LCDs to the CAC. Of note, NCDs that go before the MEDCAC are selected by the agency and it is not part of the process for every NCD.

Under the current LCD process, after the close of the comment period and the required meetings, the MAC publishes a final LCD. As stated earlier, the MAC must also respond to any comments received, via a comment/response document. A notice period of at least 45 calendar days is then required before the LCD can take effect. While it takes time for the provider community and the claims processing systems to adapt to changes in coverage, a notice period delays the date of when coverage may be become effective.

In addition to evaluating the effectiveness of certain aspects of the LCD implementation process, we are also examining a pilot project that CMS launched with a single MAC, Palmetto GBA, on November 1, 2011. While the pilot discussed in this section only includes molecular diagnostic (genetic) laboratory tests, a subset of all clinical diagnostic lab tests, we believe the pilot's design and some of the lessons learned from the pilot can be applied to all clinical diagnostic laboratory tests

For background, the universe of molecular diagnostic laboratory tests is vast and the current LCD process can be lengthy for some of these innovative tests, which are technically complex. For example, multiple molecular diagnostic tests designated to diagnose the same disease may rely on different underlying technologies and, therefore, have significantly different performance characteristics. It would not be appropriate to assume that all tests for a particular condition behave the same. Because of these complexities, we have an obligation to consider the evidence at a granular level; that is, to ensure coverage of the appropriate test for the appropriate Medicare beneficiary.

The pilot project's long-term goal was to assist clinicians by determining whether the molecular diagnostic tests they order actually perform as expected and, thus, ultimately improve clinical care. This goal stemmed from concerns that some tests were being marketed directly to physicians without information regarding the test's performance. The pilot project sought to achieve this goal by identifying all of the molecular diagnostic tests that Medicare was covering in the Palmetto MAC jurisdiction. This required the ability to uniquely identify tests through test registration and assignment of an identifier. In addition, the MAC reviewed clinical statements made by the manufacturer for each molecular diagnostic test to ensure the test was delivering what was being claimed. Essentially, the pilot project facilitated claims processing, tracked utilization, and determined clinical validity, utility and coverage through technical assessments of published test data.

As part of the pilot project, Palmetto wrote a single molecular diagnostic laboratory testing LCD that outlined the framework they would follow in determining coverage of all molecular diagnostic tests in their jurisdiction. Additionally, that LCD included a list of covered molecular diagnostic tests. Moreover, Palmetto issued several articles addressing various other aspects of the LCD implementation process, including coding guidelines, billing and medical review procedures. There is much information that is not contained in the body of an LCD that is necessary for consistent and predictable claims processing and payment.

We believe a process that ensures transparency and stakeholder participation can be achieved without utilizing the current LCD process in its entirety. Some key aspects of the process should be maintained such as allowing public comment on draft LCDs and requiring MAC responses to public comments. However, we believe other aspects could be streamlined to allow more timely decisions and a more efficient process.

2. Proposed New LCD Process for Clinical Diagnostic Laboratory Tests

After assessment of the current LCD process, the Palmetto pilot project, the requirements of the PAMA, and the vast field of clinical diagnostic laboratory tests, including molecular diagnostic tests, we are proposing a revised LCD process for all new draft clinical diagnostic laboratory test LCDs published on or after January 1, 2015. This process would carefully balance the need for an expedited process to handle the vast number of clinical diagnostic laboratory tests, including the rapidly growing universe of molecular diagnostic tests. The National Institutes of Health (NIH)-sponsored Genetic Testing Registry (GTR) currently includes 16,000 registered genetic tests for over 4,000 conditions (*www.ncbi.nlm.nih.gov/gtr/*). We have a responsibility to ensure that appropriate tests are covered by Medicare and that coverage is limited to tests for which the test results are used by the ordering physician in the management of the beneficiary's specific medical problem (as required in § 410.32(a)). Coverage for diagnostic laboratory tests may be achieved through various policy vehicles, including an NCD, LCD, or claim-by-claim adjudication at the local contractor level. For most molecular diagnostic tests, coverage has been determined by the MACs, through LCDs or claim-by-claim adjudication. Few such tests have been the subject of an NCD, to date. This concentration of coverage decisions at the local level, and the responsibility of the agency to allow coverage of appropriate tests provide additional reasons to provide MACs with a more streamlined LCD process.

Based on these considerations, we are proposing a new LCD process that would apply only to clinical diagnostic laboratory tests. Specifically, we are proposing to establish a process MACs must follow when developing clinical diagnostic laboratory test LCDs and encouraging MACs to collaborate on such policies across jurisdictions. We propose that the process apply to all new clinical diagnostic laboratory testing draft LCDs published on or after January 1, 2015. Consistent with Chapter 13, section 13.7.3 of the Medicare Program Integrity Manual (PIM), however, we further propose that this process will not apply to clinical diagnostic laboratory testing LCDs that are being revised for the following

reasons: to liberalize an existing LCD; being issued for a compelling reason; making a non-substantive correction; providing a clarification; making a non-discretionary coverage or diagnosis coding update; making a discretionary diagnosis coding update that does not restrict; or revising to effectuate an Administrative Law Judge's decision on a Benefits Improvement and Protection Act (BIPA) 522 challenge.

The proposed new process would allow any person or entity to request an LCD or the MAC to initiate an LCD regarding clinical diagnostic laboratory testing. After this external request or internal initiation, the MAC would publish a draft LCD in the Medicare Coverage Database (*http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*), thereby making the draft LCD publicly available. Next, a minimum of 30 calendar days for public comment would be required. We note that in the event that stakeholders and/or members of the public are not able to submit comments within the 30 calendar day window, the MAC would have discretion to extend the comment period. We would expect the draft LCDs to outline the criteria the MAC would use when determining whether a specific clinical diagnostic laboratory test or a group of tests are covered or non-covered. The MAC would review, analyze, and take under consideration all public comments on the draft LCD. For draft LCDs where the MAC determines that a CAC meeting would contribute to the quality of the final policy, the MAC has discretion to take draft LCDs to the CAC. In the event the MAC involves the CAC in the development of an LCD, we would require that the public comment period be extended to allow for the CAC to be held before the final policy is issued. The MAC would be required to respond to all public comments in writing and post their responses on a public Web site. As a final step, the MAC would publish the final LCD in the Medicare Coverage Database no later than 45 calendar days after the close of the comment period. We believe 45 days to be an adequate time for the MAC to take all comments under consideration, prepare responses to those comments, and develop a final policy.

The final LCD would be effective immediately upon publication. This effective date would be different than under the current LCD process (which includes a notice period of at least 45 calendar days before a final LCD is effective); however, based on our experience with NCDs, which are also effective upon publication, we believe this is an efficient mechanism to make tests available to beneficiaries more quickly.

3. Reconsideration Process

The proposed process for developing clinical diagnostic laboratory testing LCDs would not change the LCD reconsideration process as outlined in the PIM in Chapter 13. This section of the manual allows interested parties the opportunity to request reconsideration of an LCD. Under the proposed process, the MACs would continue to implement all sections of the PIM that relate to the LCD reconsideration process.

4. LCD Challenge Process

The proposed process for clinical diagnostic laboratory testing LCDs would also not change any of the current review processes available to an aggrieved party. An aggrieved party would continue to be able to challenge an LCD according to the requirements set out in 42 CFR part 426.

As discussed previously, we believe an administratively more efficient process is needed for local coverage determinations for clinical diagnostic laboratory testing. If we continue to require that MACs follow all steps in the current LCD process, we fear that LCDs will not be able to be finalized quickly enough for even a fraction of the thousands of new clinical diagnostic (particularly molecular) tests developed each year.

We believe this proposed new process for clinical diagnostic laboratory tests will allow for public dialogue, notification of stakeholders, and expedited beneficiary access to covered tests. Table 18 summarizes the differences between the current LCD process and the proposed new LCD process for the development of clinical diagnostic laboratory testing policies.

TABLE 18—COMPARISON OF CURRENT LCD PROCESS VERSUS PROPOSED LCD PROCESS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS

Current LCD process	Proposed LCD process for clinical diagnostic laboratory tests
Issue Draft LCD in Medicare Coverage Database, which identifies criteria used for determining coverage under statutory ''reasonable and necessary'' standard.	Issue Draft LCD in Medicare Coverage Database, which identifies criteria used for determining coverage under statutory ''reasonable and necessary'' standard.
Public comment period of 45 calendar days	Public comment period of 30 calendar days with option to extend.
Present LCD at CAC & discussion at open stakeholder meetings	Optional CAC meeting. No requirement for open stakeholder meeting.
Publication of Comment/Response Document and final LCD (no specified time of publication after the close of the comment period).	Publication of Comment/Response Document and final LCD within 45 calendar days of the close of the draft LCD comment period.
Notice period of 45 calendar days with the final LCD effective the 46th calendar day.	Final LCD effective on the date of publication.
Interested parties may request reconsideration of an LCD	Interested parties may request reconsideration of an LCD.
An aggrieved party may further challenge an LCD	An aggrieved party may further challenge an LCD.

In summary, we believe this proposed process would meet all the requirements of the PAMA, would be open and transparent, would allow for public input, and would be administratively efficient. We are proposing this process only for clinical diagnostic laboratory testing when coverage policies are developed by a MAC through an LCD; it would not apply to the NCD process or other vehicles of coverage including claim-by-claim adjudication. We believe the proposed process would balance stakeholders' concerns about ensuring an open and transparent process with the ability to efficiently review clinical laboratory tests for coverage. We encourage public comment on all aspects of this proposed process.

G. Private Contracting/Opt-Out

1. Background

Effective January 1, 1998, section 1802(b) of the Act permits certain physicians and practitioners to opt-out of Medicare if certain conditions are met, and to furnish through private contracts services that would otherwise be covered by Medicare. For those physicians and practitioners who opt-