# Section 3113: Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration

Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Medicare Demonstrations Group

July 2011

# Agenda

- Demonstration overview
- Demonstration Test List
- Demonstration payment rates
- Payment under the Demonstration
- Report to Congress
- Questions

# Ground Rules

- Identify yourself
- Identify your organization
- Limit comments to 2 minutes

# Legislative Mandate

**Section 3113 of the Affordable Care Act**:

- Defines certain complex laboratory test
- Defines separate payment
- Limits Demonstration to 2 years subject to a $100 million total payment limit
- Requires a Report to Congress

# Goal

To allow a separate payment to laboratories performing certain complex laboratory tests billed with a date of service that would under standard Medicare rules be bundled into the payment to the hospital or critical access hospital (CAH).

# Complex Diagnostic Laboratory Test

Defined by section 3113(a)(2) as:

1. an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay;
2. a laboratory test for which there is not an alternative test having equivalent performance characteristics;

# Complex Diagnostic Laboratory Test

3. billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code;
4. approved or cleared by the Federal Drug Administration or is covered under Medicare; and
5. described in section 1861(s)(3) of the Act.

# Temporary Demonstration G-codes

- meet the section 3113 criteria except that they are billed using NOC codes
- the current payment rate setting method of gap filling and cross walking is not applicable
- Supporting Information due to CMS by August 1

# Temporary Demonstration G-codes

| | Diagnosis | Diagnosis: Primary vs Secondary Cancer | Prognosis: Risk Assessment | Treatment: Response to agent |
|---|---|---|---|---|
| **Analysis of gene protein expression** | | | | |
| **Topographic genotyping** | | | | |
| **A cancer chemotherapy sensitivity assay** | | | | |

# Demonstration Test List

- 36 diagnostic laboratory tests with assigned HCPCS codes
- Temporary Demonstration G-codes
- Demonstration payment rate

# Payment Rates

- Each code that appears on the Demonstration Test List will have one corresponding payment rate
- Payment rates will not vary across region or MAC
- Payment rates to be determined

# Date of Service

- When a test is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital, the hospital or CAH must bill Medicare for a clinical laboratory test provided by a laboratory and the hospital or CAH would in turn pay the laboratory if the test was furnished under arrangement.

# Payment under the Demonstration

- Lab may bill Medicare directly for a test which is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital or CAH
- Demonstration "Project Identifier 56" on claim
- Test Code must appear on the Demonstration Test List
- All other Medicare payment policy edits apply

# Payment under the Demonstration

- All Medicare Administrative Contractors (MACs) are instructed to make and monitor payments
- Once the first of either $100 million is expended or 2 years passes, payment for these tests will be made under the existing non-demonstration process.
- Payment under the Demonstration begins on January 1, 2012.

# Report to Congress

An assessment of the impact on:

- access to care,
- quality of care,
- health outcomes, and
- expenditures.

# Questions?