Modernizing Medicare Billing Requirements for Precision Diagnostics Performed on Outpatient Specimens

CY 2018 HOPPS Rulemaking

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21st centurymedicine

Coalition for 21st Century Medicine

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Summary of Key Points

- **Outdated billing regulations create barriers to personalized medicine**
  - Interaction of Date of Service and Under Arrangements regulations forces hospitals to bill for outpatient tests that they do not perform
  - Results in delays in diagnosis and treatment for Medicare patients
- **Support CMS effort to revise laboratory date of service policy in HOPPS Proposed Rule**
  - Support CMS efforts to modernize billing jurisdiction rules for precision tests
  - Final Rule should permit performing lab to bill for precision diagnostics performed on outpatient sample
- **Recommend technical clarifications to regulatory language to address three concerns with Proposed Rule:**
  - Include all molecular pathology tests, ADLTs, and MAAAs performed on tissue and liquid specimens collected from outpatients
- **CMS can finalize revision through "Under Arrangements" or "Date of Service" regulations**

Date of Service Policy Stems from Interaction of Two Medicare Regulations

- **1. Date of Service regulation defines when test furnished for Medicare payment purposes**
  - For tests ordered within 14 days of outpatient encounter date of service is date of specimen collection
  - 42 CFR 414.510
- **2. Under Arrangements regulations require hospitals to bill for services furnished to outpatients on same date of service**
  - Even if the laboratory test is **not** performed by the hospital
  - 42 CFR 410.42 and 411.15(m)
- **Problem: Hospital must bill for precision tests ordered within 14 days of encounter even when hospital does not perform test**
  - Includes tests paid separately from outpatient service on CLFS because pattern of clinical use makes them unconnected to primary service

Billing Complexities and Administrative Burden of Current Policy

- **Billing complexities of date of service policy lead hospitals to delay ordering precision diagnostics**
  - Delay in precision diagnostic testing delays initiation of treatment and worsens patient health outcomes
  - Commercial and Medicare Advantage plans allow performing lab to bill directly
- **Barrier to goal of promoting personalized medicine**
  - Disproportionate effect on smaller labs performing innovative tests
- **At odds with clinical rationale for separate CLFS payment for certain outpatient precision diagnostics**

Proposed Rule Solicits Comments on Potential Revisions to DOS Policy

- **CMS includes extensive discussion on administrative difficulties posed by current date of service policy**
  - Notes stakeholder concerns about delays in access to care and impact on development of precision medicine
- **Agency requests specific comments on potential modification to DOS policy that would:**
  - Allow labs to bill Medicare directly for tests when specimen taken during hospital outpatient procedure and test ordered after discharge
  - Agency also inviting comments on alternative approaches
- **CMS would consider finalizing two options for modification**
  - Revise Date of Service regulations
  - Revise Under Arrangements regulations

Support CMS' Effort to Update Billing Jurisdiction Requirements

- **Stakeholders agree current date of service policy restricts patient access to precision medicine**
  - Date of service policy inconsistent with rationale for separate payment of precision diagnostics on CLFS
- **Support CMS' approach of permitting performing lab to bill for precision tests on outpatient specimens**
  - Recommend technical modifications to ensure revisions encompass all precision tests unconnected to primary outpatient service
- **Regulatory reform agenda supports revision**
  - Aligns with key Administration goal of modernizing "outdated, unnecessary, or ineffective" regulations
- **No budget impact**
  - Tests already separately payable on CLFS whether billed by hospital or lab

Two Regulatory Options For Final Rule

Option 1: Revise Under Arrangements regulations

Add new 42 C.F.R. 410.42(b)(8) and 411.15(m)(3)(vii)

Rationale:

- ***Would maintain same date of service for inpatient and outpatient specimens***
- ***Aligns with CMS' original approach to bundling diagnostic tests***

Option 2: Revise Date of Service regulations

Add new 42 C.F.R. 414.510(b)(5)

Rationale:

- ***Pre-2001, CMS permitted date of service to be performance date***
- ***CMS modernized date of service regulations in 2006, consistent to update in 2017***

C21 supports either modification with certain technical clarifications

Technical Clarification #1: Include Molecular Pathology, ADLTs, and MAAAs

- **Support CMS' inclusion of molecular pathology tests and ADLTs in billing jurisdiction revision**
  - Consistent with existing CMS outpatient laboratory packaging policy that these tests have different pattern of clinical use from routine testing
- **Include in revision all ADLTs under PAMA**
  - ADLTs are all "offered and furnished only by a single laboratory"
- **Include in revision all MAAAs**
  - DNA- and RNA-based MAAAs included as molecular pathology tests
  - Protein-based MAAAs have clinical pattern of use as DNA- and RNA-based counterparts
  - Included with DNA- and RNA-based MAAAs in statutory and final regulatory ADLT definition under PAMA

Include all molecular pathology tests, ADLTs and MAAAs in regulatory revision

Technical Clarification #2: Remove Order Date Requirement for Laboratory Billing

- **Proposed Rule language permits performing lab to bill only if test "ordered" following date of discharge**
  - Order date only relevant for stored tissue specimens
- **Order date requirement would exclude tests performed on liquid specimens**
  - Liquid-based tests ordered on or before date of specimen collection for clinical and practical reasons
- **Rationale for policy revisions applies equally to liquid-based tests**
  - Similarly unconnected with primary outpatient service

Remove "order date" requirement for laboratory billing

Technical Clarification #3: Specimen Collection Appropriate During Encounter

- **Potential revision in Proposed Rule requires specimen collection be "medically inappropriate" outside encounter**
  - Language taken from current "14 Day Rule" regulation for stored specimens
- **Avoid exclusion of liquid-based tests by requiring that collection be "medically appropriate" during the encounter**
  - May lead hospitals to require patients to go elsewhere for blood draw
  - Presents access issues for patients with limited mobility

Require that it be "medically appropriate" to have collected sample during encounter

Conclusion

- **C21 supports finalizing modification to either Under Arrangements or Date of Service regulations**
  - Recommend technical clarifications to ensure performing lab can bill for tests unconnected with outpatient service
- **Proposed Rule provides stakeholders sufficient notice that either change is possible**
  - Extensive discussion explicitly mentions possibility of revising Date of Service and Under Arrangements regulations
- **Finalizing either modification would represent logical outgrowth of Proposed Rule**

Requested Action Summary

- The final OPPS update for CY 2018 should include regulatory changes to either 42 C.F.R. 410.42(b)(8) and 411.15(m)(3)(vii) or 42 C.F.R. 414.510(b)(5) to allow labs to bill Medicare directly for certain tests.
- The regulatory changes should allow direct billing for molecular pathology tests, Advanced Diagnostic Laboratory Tests (ADLTs) and Multianalyte Assays with Algorithmic Analysis (MAAAs).
- The criteria for identifying an eligible test should not include a requirement that permits a performing lab to bill only if test "ordered" following date of discharge. CMS should remove an "order date" requirement for direct laboratory billing.