Medicare Coverage & Reimbursement:
What TC's Need to Know in 2017

NATIONAL MARROW DONOR PROGRAM®

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Today's Webinar

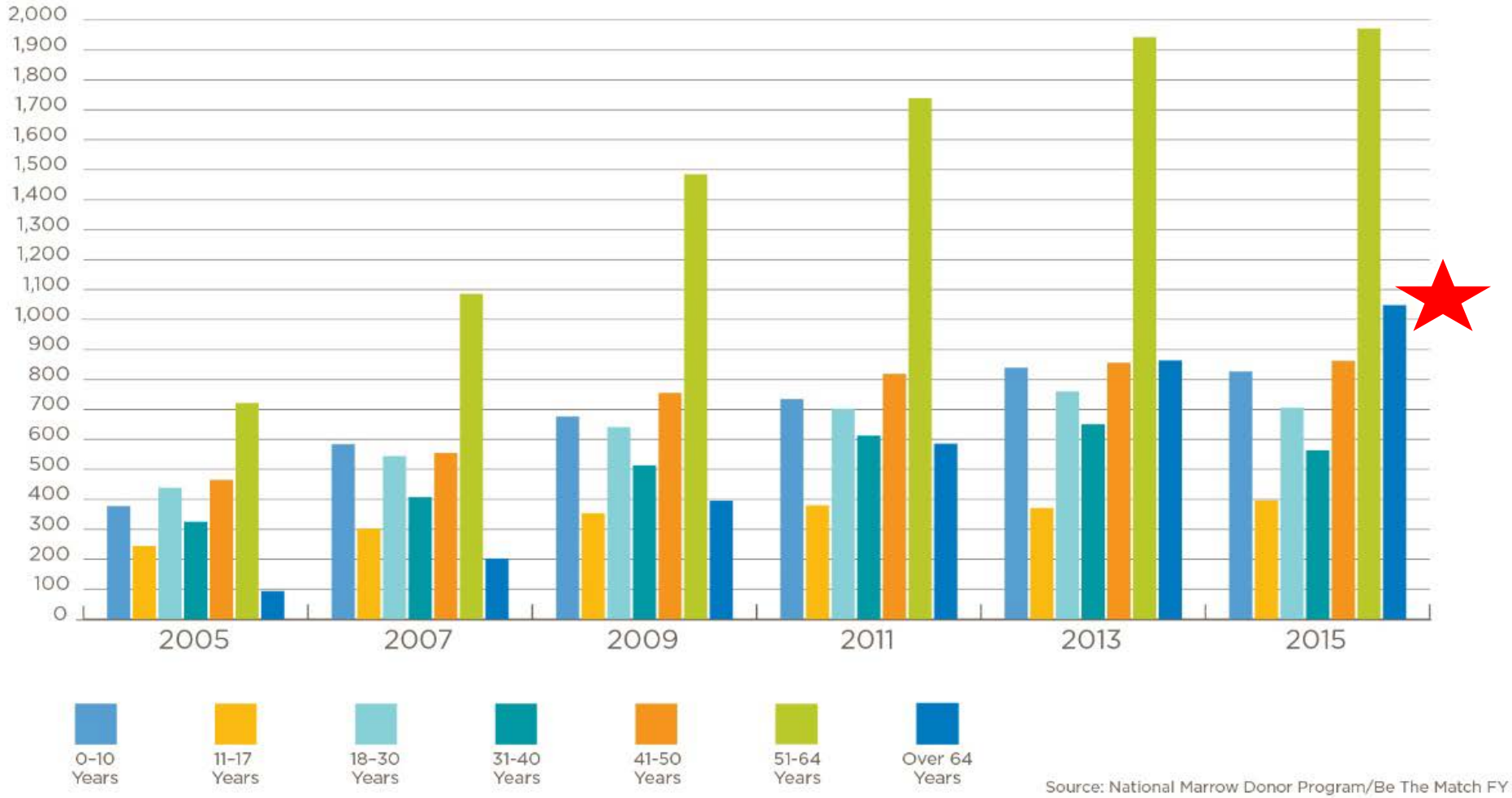
Medicare Coding and Reimbursement

- Jugna Shah, Nimitt Consulting
- Valerie Rinkle, Nimitt Consulting

Medicare Coverage and Advocacy

- Kathy Lester, Lester Health Law

Medicare Matters



Source: National Marrow Donor Program/Be The Match FY 2015

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Review of Centers for Medicare and Medicaid Services (CMS) in Action…

- CMS has responded to advocacy efforts from the NMDP, ASBMT, and providers since 2010 and has issued the following changes:
  - In FY 2010: CMS split MS-DRG 009 into two DRGs for allo (014) and auto (015) cases
  - In FY 2011: CMS divided MS-DRG 015 to recognize complications and comorbidities into MS-DRG 016 w/CCs and MS-DRG 017 for no CCs and also requested hospitals report donor source procedure codes
  - In FY 2016: CMS indicated providers should use cost report lines 62 and 63
  - In CY 2017: CMS finalized a "bundled" type payment along with other changes
  - Others
    - Claims processing manual changes have been made
    - Coverage expanded
    - Discussions with the NMDP about improving reimbursement & coverage

Medicare Coding & Reimbursement

Jugna Shah, MPH
Valerie Rinkle, MPA
Nimitt Consulting

Current FY 2017 HCT MS-DRGs

014

Allogeneic Bone Marrow Transplant

No breakout for related or unrelated

Relative Weight 11.6407

016

Autologous Bone Marrow Transplant with MCC/CC

With

CC/MCC (driven by secondary dx codes)

Relative Weight 6.1050

017

Autologous Bone Marrow Transplant without MCC/CC

Without

CC/MCC (driven by secondary dx codes)

Relative Weight

4.0701

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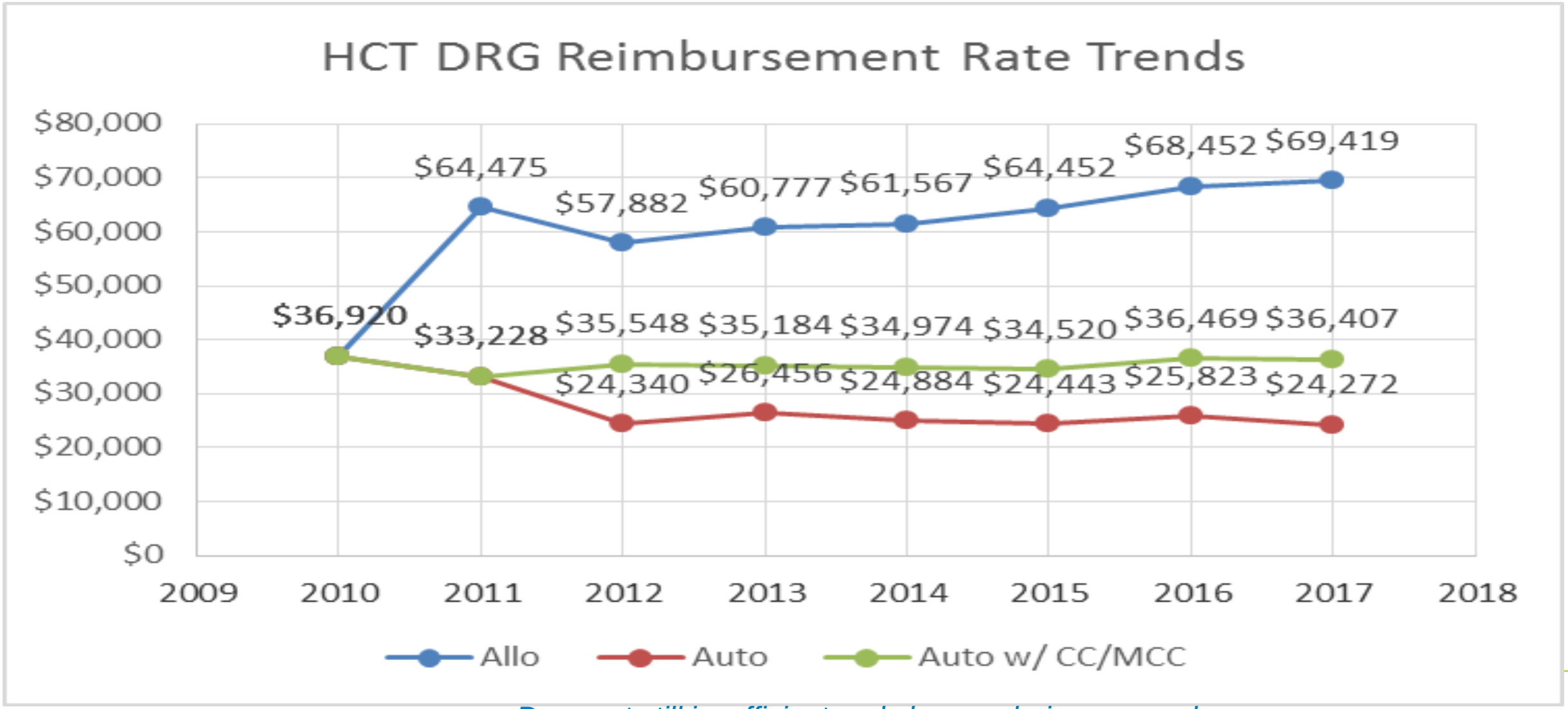
Inpatient MS-DRG Reimbursement Rate Trends



Payment still insufficient and changes being pursued

Allogeneic Reporting Summary Inpatient Data: Revenue Code 0819 and Donor Code

Data Year	2007	2009	2011	2012	2013	2014	2015
Total Allogeneic Transplants (MS-DRG 014)	329	495	545	600	702	801	**924**
% reporting 0819	38%	68%	72%	75%	72.80%	75%	**79%**
Median 0819 charges reported (w/o $0 claims)	$8,000	$48,000	$51,800	$50,349	$56,380	$62,019	**$56,177**
% reporting donor source code	N/A	69%	72%	75%	73.10%	76%	**71%**

Source: CMS MedPar Files (FY 2017 payment come from 2015 data) for non-exempt providers

The Return of ICD-10 Donor Source Codes

ICD-9

- 00.91(related donor)
- 00.92 (unrelated donor)

ICD-10 Related

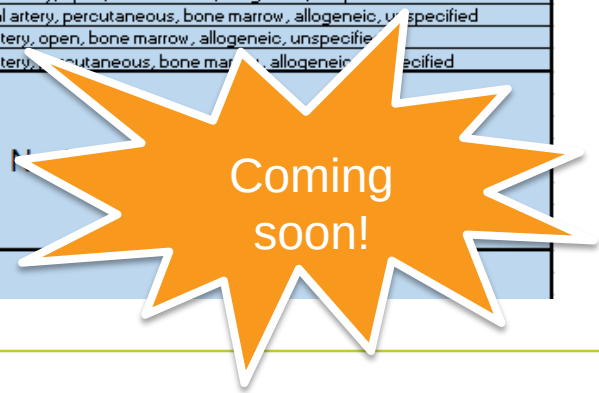
- 30243G2 – Allo related bone marrow via percutaneous venous central line infusion
- 30243X2 – Allo related cord blood via percutaneous venous central line infusion
- 30243Y2 – Allo related peripheral stem cells via venous central line infusion

ICD-10 Unrelated

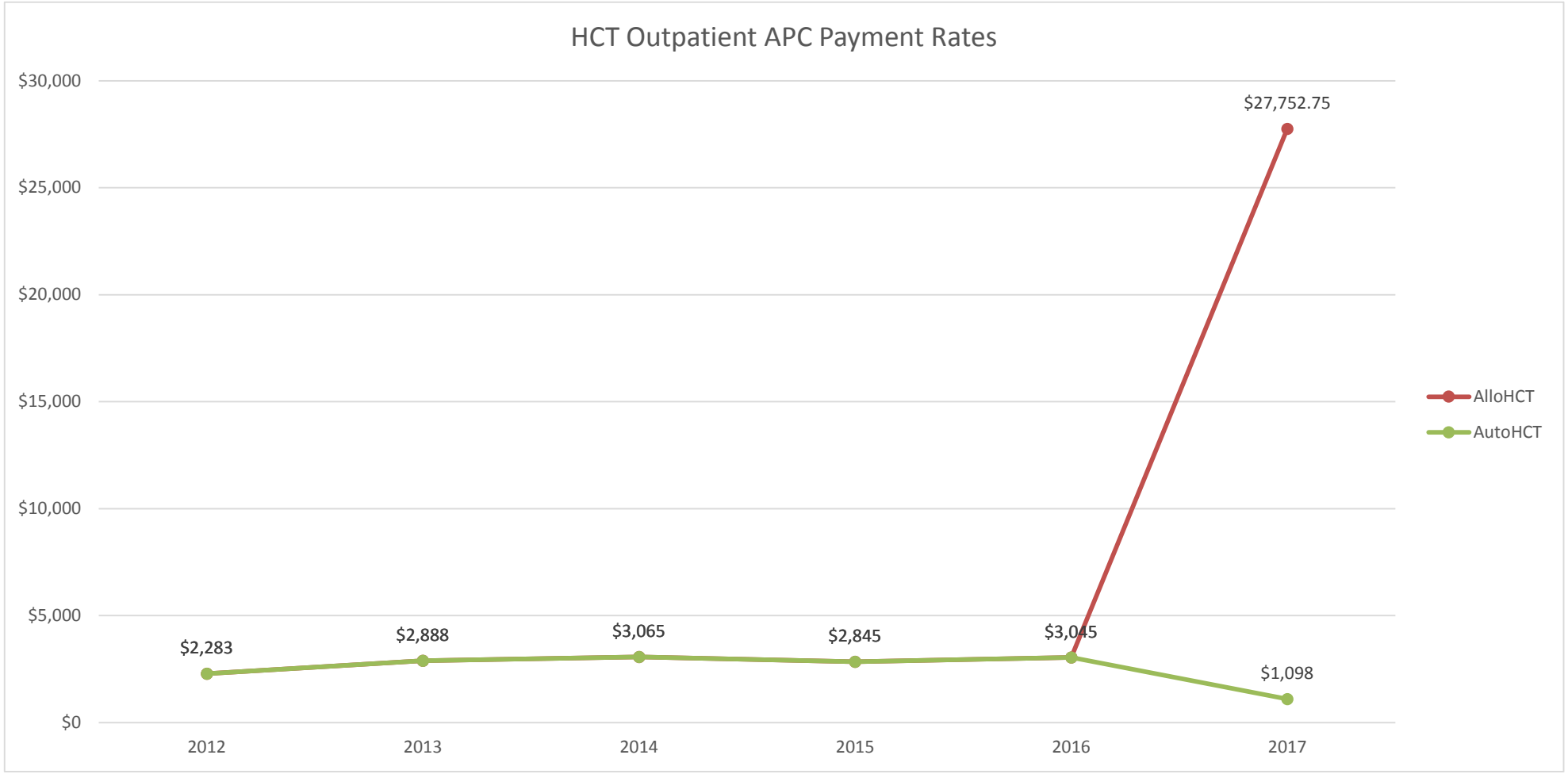
- 30243G3 – Allo unrelated bone marrow via percutaneous venous central line infusion
- 30243X3 – Allo unrelated cord blood via percutaneous venous central line infusion
- 30243Y3 – Allo unrelated peripheral stem cells via venous percutaneous central line

Other 2017 ICD-10 Updates

ICD-9-CM	2016 ICD-10-PCS	2016 ICD-10-PCS Description	2017 ICD-10-PCS	2017 ICD-10-PCS Description
Transplant				
41.01 Autologous **bone marrow** transplant without purging	30230G0	Peripheral vein, open, bone marrow, autologous	No Change from 2016	
	30233G0	Peripheral vein, percutaneous, bone marrow, autologous		
	30240G0	Central vein, open, bone marrow, autologous		
	30243G0	Central vein, percutaneous, bone marrow, autologous		
	30250G0	Peripheral artery, open, bone marrow, autologous		
	30253G0	Peripheral artery, percutaneous, bone marrow, autologous		
	30260G0	Central artery, open, bone marrow, autologous		
	30263G0	Central artery, percutaneous, bone marrow, autologous		
41.02 Unrelated Allogeneic **bone marrow** transplant with purging	30230G1	Peripheral vein, open, bone marrow, nonautologous	30230G3	Peripheral vein, open, bone marrow, allogeneic, unrelated
	30233G1	Peripheral vein, percutaneous, bone marrow, nonautologous	30233G3	Peripheral vein, percutaneous, bone marrow, allogeneic, unrelated
	30240G1	Central vein, open, bone marrow, nonautologous	30240G3	Central vein, open, bone marrow, allogeneic, unrelated
	30243G1	Central vein, percutaneous, bone marrow, nonautologous	30243G3	Central vein, percutaneous, bone marrow, allogeneic, unrelated
	30250G1	Peripheral artery, open, bone marrow, nonautologous	30250G3	Peripheral artery, open, bone marrow, allogeneic, unrelated
	30253G1	Peripheral artery, percutaneous, bone marrow, nonautologous	30253G3	Peripheral artery, percutaneous, bone marrow, allogeneic, unrelated
	30260G1	Central artery, open, bone marrow, nonautologous	30260G3	Central artery, open, bone marrow, allogeneic, unrelated
	30263G1	Central artery, percutaneous, bone marrow, nonautologous	30263G3	Central artery, percutaneous, bone marrow, allogeneic, unrelated
No equivalent ICD 9 code	No equivalent 2016		30230G2	Peripheral vein, open, bone marrow, allogeneic, related
			30233G2	Peripheral vein, percutaneous, bone marrow, allogeneic, related
			30240G2	Central vein, open, bone marrow, allogeneic, related
			30243G2	Central vein, percutaneous, bone marrow, allogeneic, related
			30250G2	Peripheral artery, open, bone marrow, allogeneic, related
			30253G2	Peripheral artery, percutaneous, bone marrow, allogeneic, related
			30260G2	Central artery, open, bone marrow, allogeneic, related
			30263G2	Central artery, percutaneous, bone marrow, allogeneic, related
No equivalent ICD 9 code	No equivalent 2016		30230G4	Peripheral vein, open, bone marrow, allogeneic, unspecified
			30233G4	Peripheral vein, percutaneous, bone marrow, allogeneic, unspecified
			30240G4	Central vein, open, bone marrow, allogeneic, unspecified
			30243G4	Central vein, percutaneous, bone marrow, allogeneic, unspecified
			30250G4	Peripheral artery, open, bone marrow, allogeneic, unspecified
			30253G4	Peripheral artery, percutaneous, bone marrow, allogeneic, unspecified
			30260G4	Central artery, open, bone marrow, allogeneic, unspecified
			30263G4	Central artery, percutaneous, bone marrow, allogeneic, unspecified
41.03 Allogeneic bone marrow transplant without purging	30230G1	Peripheral vein, open, bone marrow, nonautologous	N	
	30233G1	Peripheral vein, percutaneous, bone marrow, nonautologous		
	30240G1	Central vein, open, bone marrow, nonautologous		
	30243G1	Central vein, percutaneous, bone marrow, nonautologous		
	30250G1	Peripheral artery, open, bone marrow, nonautologous		
	30253G1	Peripheral artery, percutaneous, bone marrow, nonautologous		
	30260G1	Central artery, open, bone marrow, nonautologous		
	30263G1	Central artery, percutaneous, bone marrow, nonautologous		
	30230Y0	Peripheral vein, open, stem cells, hematopoietic, autologous		
	30233Y0	Peripheral vein, percutaneous, stem cells, hematopoietic, autologous		



Outpatient APC Reimbursement Rate Trends



CY 2017 Medicare Outpatient Changes

Four Key Changes Made

New Comprehensive APC (C-APC) 5244 assigned to CPT 38240 with a payment of $27,752

New revenue code 0815 required to report charges for allogeneic donor search and cell acquisition costs

New edit Starting January 1, 2017 requiring revenue code 0815 when CPT code 38240 is reported

New dedicated cost center to capture costs for all donor related items and services; cost report line 77 and cost center code 07700

CY17 Outpatient Payment

New C-APC 5244

- CY16 payment rate: $3,045
- CY17 proposed payment rate: $15,267
- CY17 final payment rate: **$27,752**
  - 9 fold increase from the 2016 payment rate
  - CMS calculated the CY 2017 C-APC payment rate using only claims with both CPT code 38240 and revenue code 0819
  - The C-APC payment is intended to cover the procedure, all donor search and cell acquisition services, other services such as labs, visits, etc. billed on the same claim etc.

Revenue Code Reporting Changes

New revenue code 0815 required

- Revenue code 0815 released by the National Uniform Billing Committee (NUBC)
- Revenue code 0815 replaces revenue code 0819
- Revenue code 0815 is mandatory since Medicare will edit for its presence starting January 1, 2017
- If revenue code 0815 is missing on a claim where CPT code 38240 is reported, CMS will return the claim to the provider

081x Acquisition of Body Components

The acquisition and storage costs of body tissue, bone marrow, organs and other body components not otherwise identified used for transplantation.

SubC	Subcategory Definition	Standard Abbreviation	Unit	HCPCS
0	General Classification	ORGAN ACQUISIT		Y
1	Living Donor	LIVING DONOR		Y
2	Cadaver Donor	CADAVER DONOR		Y
3	Unknown Donor	UNKNOWN DONOR		Y
4	Unsuccessful Organ Search - Donor Bank Charges	UNSUCCESSFUL SEARCH		Y
5	Stem Cells - Allogeneic (Effective 1/1/17)	STEM CELL		Y
6-8	RESERVED			
9	Other Donor	OTHER DONOR		Y

Notes:
Living donor is a living person from whom an organ is collected and used for transplantation purposes.

Cadaver is an individual pronounced dead according to medical and legal criteria, and whose organs may be harvested for transplantation.

Unknown is used whenever the status of the individual source cannot be determined. Use the other category whenever the organ is non-human.

Revenue Code 0814 is used only when costs incurred for an organ search do not result in an eventual organ acquisition and transplantation.

Cost Report Changes

Cost Report

- Cost center 77
  - new standard cost center for “Allogeneic Stem Cell Acquisition,” added to Worksheet A (and applicable worksheets) for providers to record allogeneic stem cell acquisition costs
- Cost center line 77
- Cost center code 07700

Next Steps for Transplant Centers…

- Update revenue code from 0819 to 0815 starting January 1, 2017
- Implement cost center line 77
- Consider replicating CMS' edit with a pre-bill edit of your own to ensure that revenue code 0815 is present when you bill CPT code 38240
- Review your mark-up practice for purchased services (i.e., NMDP cell acquisition)
- Ensure that processes are in place so that donors are never charged
- Consider setting up a dedicated general ledger department for donor related expense and revenue, for NMDP and other purchased services related to HSCT
- Develop a process to reclassify revenues and expenses associated with in-house donor services so that there is a proper matching in the cost report of all charges and costs associated with HSCT
- Conduct an audit to ensure that all charges are being captured and reported appropriately

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Look for a Medicare CDM and Cost Report webinar in early 2017!

Stay Tuned for More from CMS…

- Inpatient and outpatient billing and reporting rules are basically the same, even though CMS only discussed revenue code 0815 and cost report line 77 in the outpatient rule – expect to see changes in official CMS guidance documents and also the next IPPS rule

  - End of year transmittals
  - *CMS Publication 100-04, Chapter 3 Section 90.3.3.A, 90.3.3.B,*
  - *CMS Publication 100-04, Ch. 4, Section 231.11*

Look for a Medicare CDM and Cost Report webinar in early 2017!

Summary

Transplant providers and CMS have made improvements, but there is still more to be done by both!

By Providers

- Strive for 100% reporting of revenue code 0815
- Strive for 100% reporting of donor source code
- Report all donor related charges
- Make appropriate cost report changes
- Review existing mark-up practices taking into consideration CMS' rate-setting methodology
- Get involved/stay involved in advocacy efforts

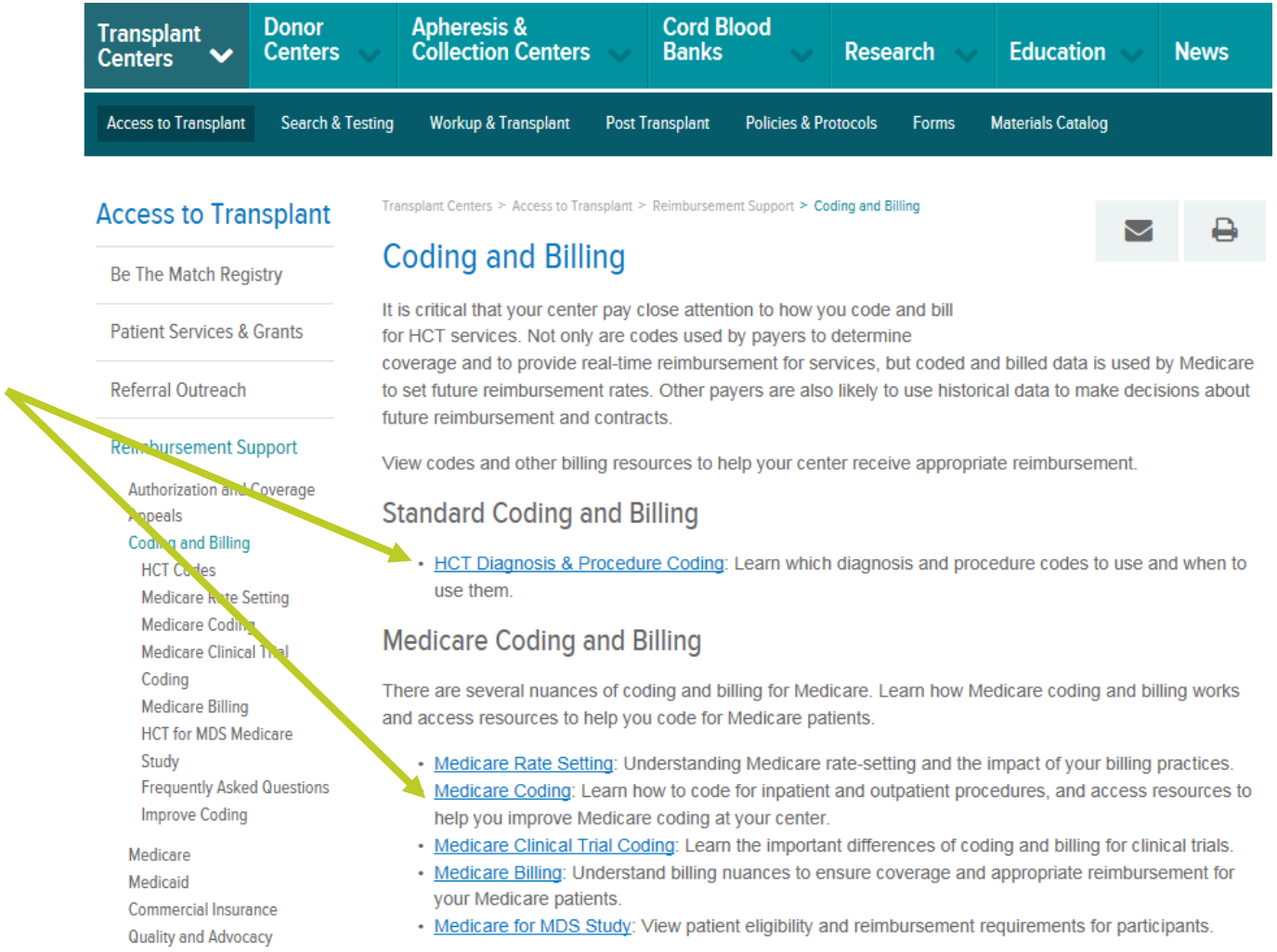
By CMS

- Provide more/clearer guidance to providers
- Recognize the true component costs of transplant, specifically cell acquisition/procurement costs
- Recognize cancelled transplant costs directly
- Continue improving payment methodologies

Reimbursement Resource Center Coding & Billing

Look for updates soon to reflect the changes discussed today

- Find updated ICD coding crosswalks & donor source coding
- Outpatient billing changes instructions
- Find answers to frequently asked questions



Medicare Coverage & Advocacy

Kathy Lester, JD, MPH
Lester Health Law, PLLC

Look for more information about the recent MLN/OIG report from the NMDP **soon!**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Medicare Learning Network

MLN Matters®

CMS

Official Information Health Care Professionals Can Trust

MLN Matters® Number: SE1624 | **Related Change Request (CR) #: N/A**

Article Release Date: November 22, 2016 | **Effective Date: N/A**

Related CR Transmittal #: N/A | **Implementation Date: N/A**

Office of Inspector General Report: Stem Cell Transplantation

Provider Types Affected

This article is intended for providers billing Medicare Administrative Contractors (MACs) for services related to stem cell transplantation.

Provider Action Needed

The Office of the Inspector General (OIG) recently completed a review of Medicare claims related to stem cell transplants. This article is intended to address issues of incorrect billing as a result of the February 2016 OIG report and to clarify coverage of stem cell transplantation. This article does not introduce any new policies. It is intended to clarify the billing for stem cell services.

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2017 Advocacy Efforts: Parity with Solid Organ Donors in IPPS

- Living donor regulatory policy
  - Kidney acquisition (living donors) treated apart from the DRG and compensate the hospital for reasonable expenses (42 CFR § 412.100)
  - HCT acquisition accounted for within the DRG (*Claims Processing Manual 90.3.3)*
- Similar services
  - Tissue typing, donor evaluation, excising organ, operating room/ancillary services, preservation costs, registry costs, transportation, lab services

Medicare Coverage: Allogeneic HCT

Current NCD

- Acute leukemia
- Wiskott Aldrich
- Severe combined immunodeficiency disorder (SCID)
- Aplastic anemia

CED

- Myelodysplastic syndrome (MDS)
- Sickle cell disease (approved)
- Myelofibrosis (approved)
- Multiple myeloma

Non-Covered "silent" Indications

- Lymphoma
- Others: dozens of indications remain in limbo

New CED Updates

Sickle cell disease

- BMT CTN 1503
- Second study under development

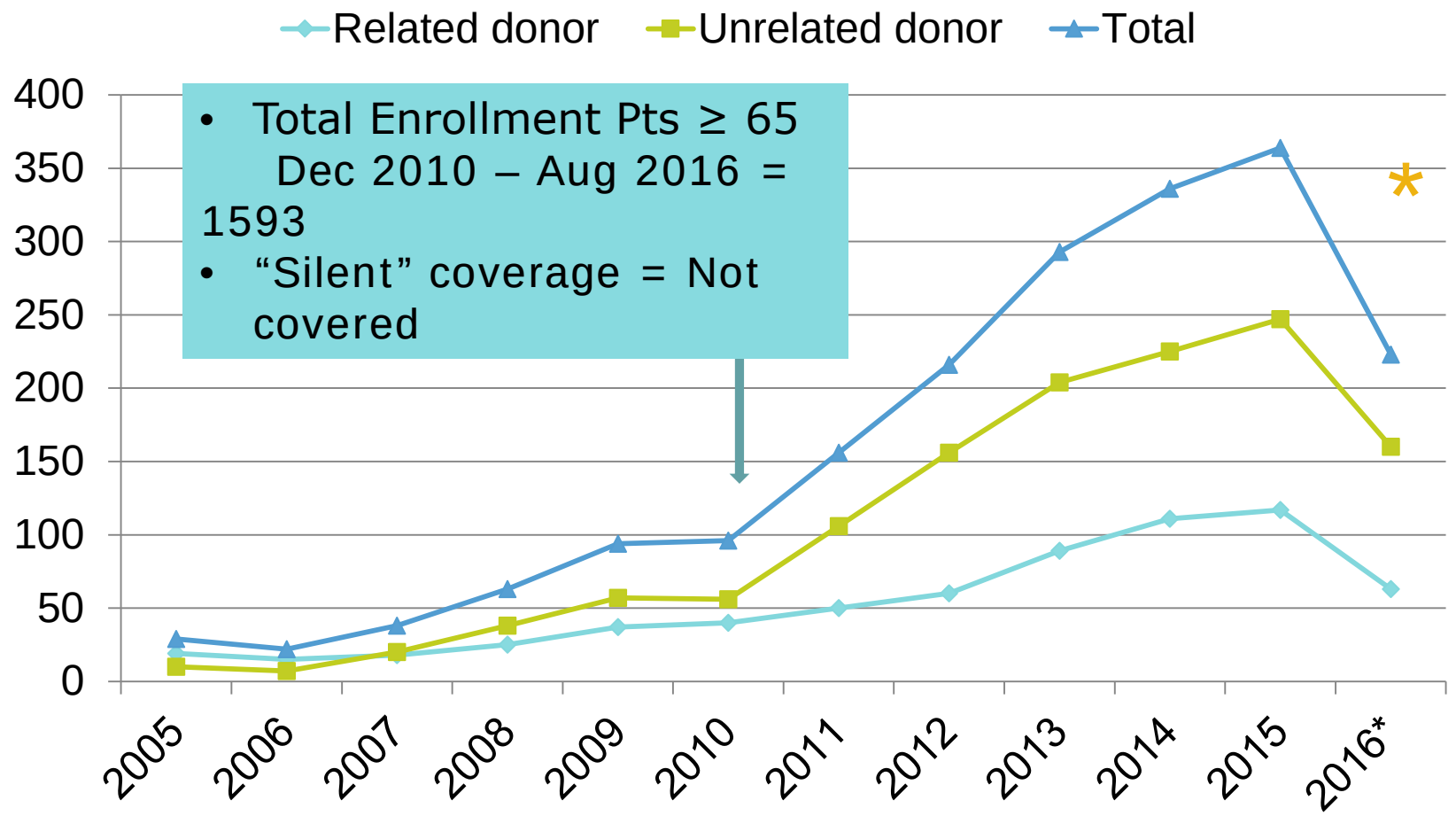
Myelofibrosis

- Study approved by CMS
- Updates forthcoming

Multiple myeloma

- Study development in progress

US Allogeneic Transplants for MDS in Patients Older than 65 years, 2005-2016



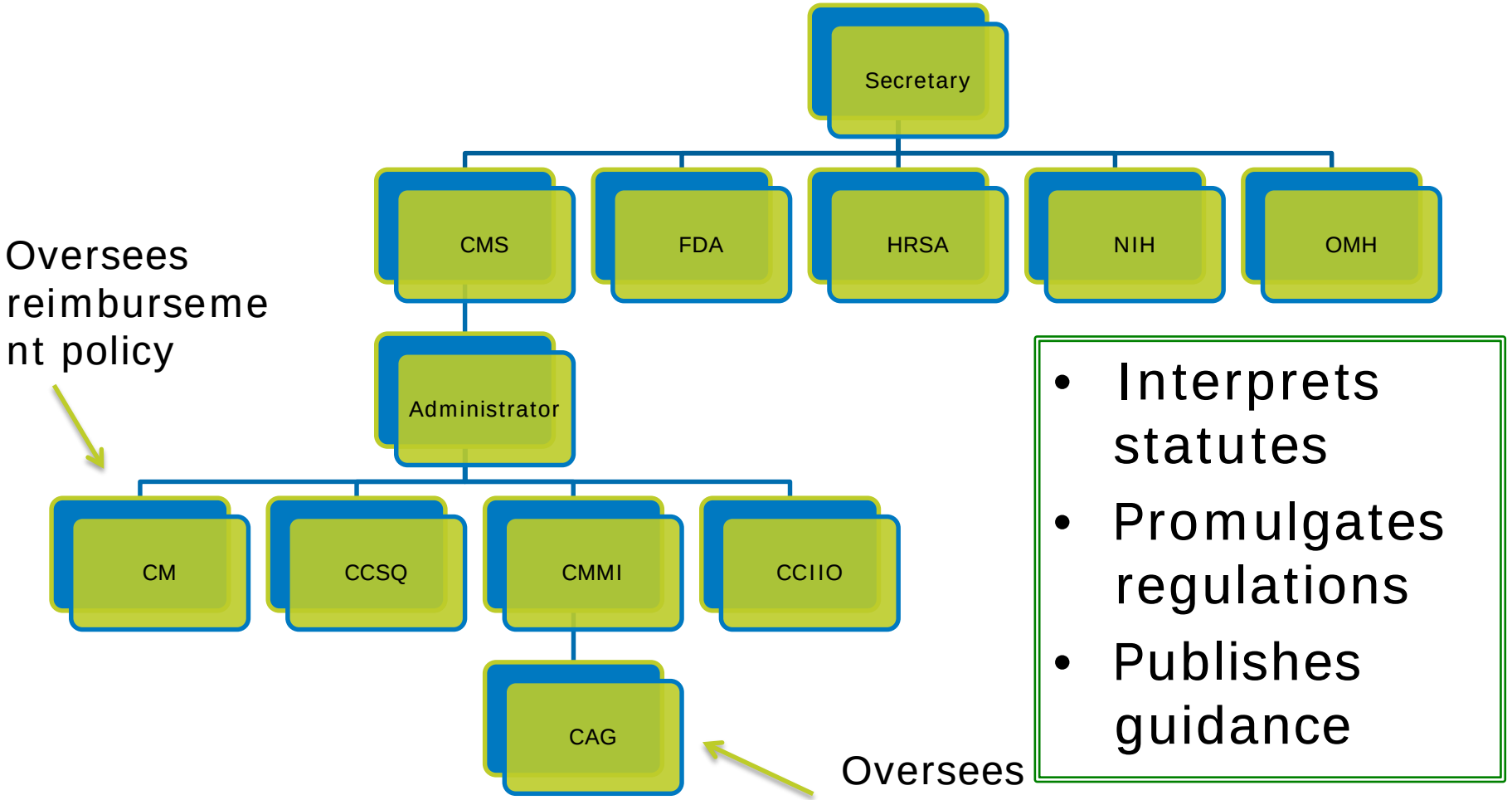
*Data for 2016 are incomplete

Medicare Coverage: What's Next?

- For indications for which coverage exists
  - Refine CEDs to address requirements that disrupt access
  - Ensure ability to continue to provide access to transplant once data points reported to CMS
  - Open studies for indications when there are none
- Address indications for which there is no CED
  - Identify critical indications
  - Develop recommendations for new pathway for coverage when limited number of patients

How to Get Involved

Understanding How Medicare Reimbursement and Coverage Policies Are Governed



Medicare Reimbursement Policy – Rulemaking

Applies to both Coverage and Payment Policies

- Congress must provide authority to Agency to act
- HHS implements statutory instructions through notice-and-comment rulemaking
- HHS publishes guidance to provide further policy clarifications; sometimes comment opportunity

What Is a Rule?

Rules

- Of general or particular applicability and future effect
- Implement, interpret, or prescribe law or policy or describe an agency's organization, procedure, or practice requirements
- Includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefore or of valuations, costs, or accounting, or practices bearing on any of the foregoing

Governed by

- Administrative Procedures Act (APA)
- Authorizing statutes
- Regulatory Flexibility Act (RFA)
- Paperwork Reduction Act (PRA)
- Federal Advisory Committee Act (FACA)
- Congressional Review Act (CRA)

The Rulemaking Process

- Provided by the Congress through statute
- Drafted by agency
- Opportunity for interested parties to opine
- Issued by the agency
- Codified in CFR
- Guidance issued by the agency to clarify rules

Coverage determinations outside of the rulemaking process; but may also provide a comment and response period

Agency Must Have Statutory Authority to Develop Regulations

Specific Issue Authority

- Congress passes legislation and President signs into law
- Statute provides framework for Agency rulemaking
- For Medicare, the statute is the Social Security Act

Administrative Procedures Act

- Requires notice and comment rulemaking
- Process requires sufficient notice
- Requires agency to review and consider comments

Agencies may also publish an Advanced Notice of Proposed Rulemaking to solicit input before a Proposed Rule is released

Developing and Publishing a Proposed Rule

Purpose

- To announce and explain Agency's plan to address a problem or accomplish a goal

Structure

- Preamble summarizes the proposals
- Proposed regulatory text
- Legal authority
- Impact analysis

Publication

- Federal Register

Engaging in the Comment Period

Mandated

- APA requires Agency to seek comments on proposed rules

Period

- Usually from 30 to 60 days
- May be longer or shorter

Consideration

- Required to consider all timely filed comments
- Not required to review those filed late

Critically important to comment

Final Rules Establish Binding Policies

Mandated	• Agency must promulgate regulations in final form for it to be legally binding
Timing	• May be required by statute • Otherwise no specific timeframe for publications is mandated
Structure	• Preamble responds to comments and summarizes final regulations • Basis and purpose of the regulations • Effective date • Final regulatory text

Agency may also issue Interim Final Rules – effective immediately upon publication; may adjust if public comment warrants

What Happens After a Rule is Finalized

Congress

- Rules must be submitted to the Congress for review
- For major rules, 60 day review period
- May prevent from taking effect

Codified

- Regulatory text becomes part of the CFR
- Preamble and response to comments are not included

Guidance

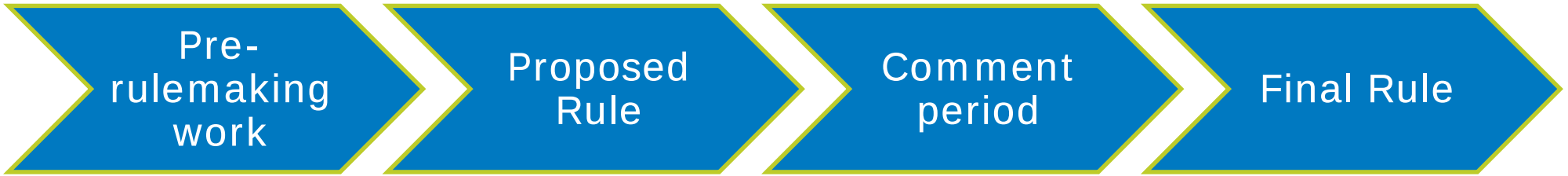
- Provide clarification
- Comes in many forms
- No notice and comment requirement

In the Context of Medicare: General Payment Policy Timeline

Fiscal Year Rules

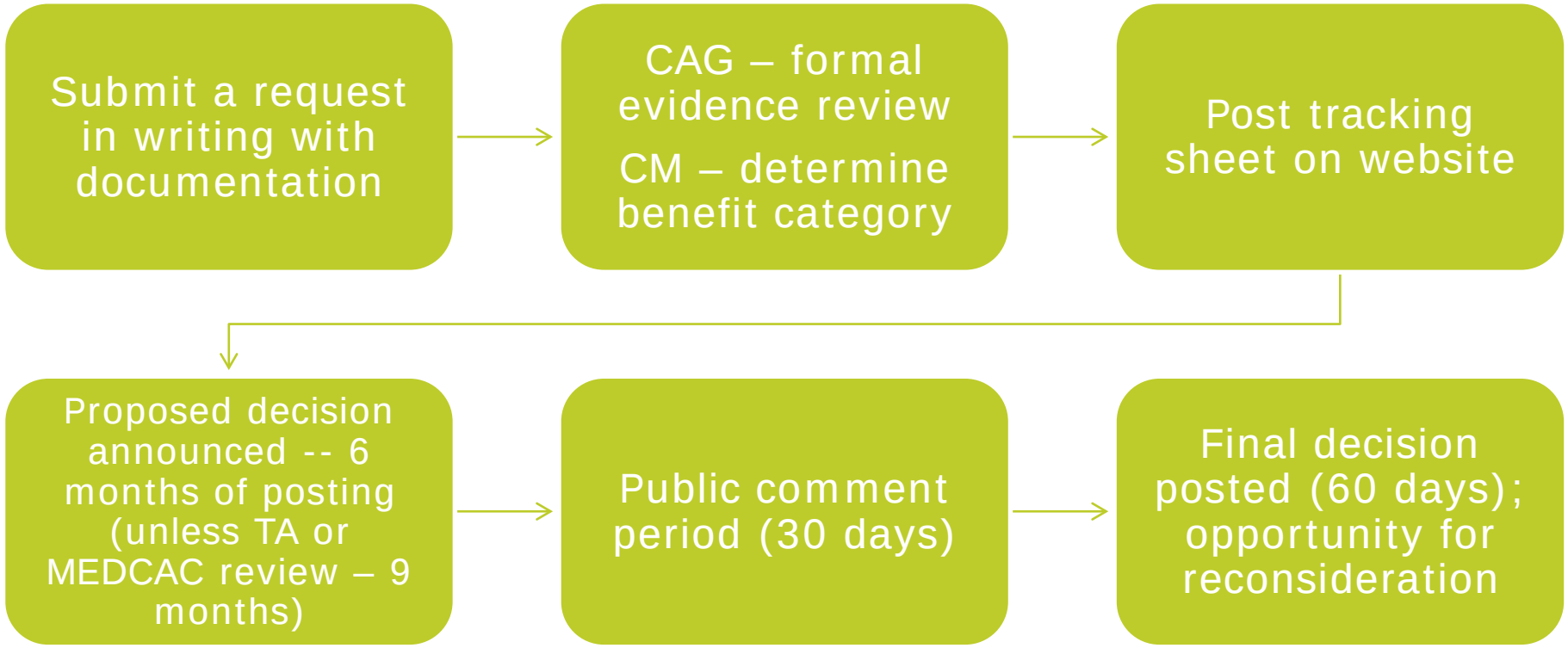
- November - February
- April
- 60 days (April – June)
- August

Calendar Year Rules



- December - March
- July
- 60 days (July–August)
- November

Coverage Process Takes Time & Support



Outcomes: (1) NCD; (2) noncoverage NCD; or (3) NCD with limitations/CED
If not Medicare, then can have local coverage determinations

May Need to Engage the Congress

Establish authority

- Create and pass statutes
- Modify authority that changes outcome of rules

Regulatory role

- Briefed by Agency staff prior to release of the proposed and final rules
- May weigh-in during comment period
  - Formal comment letters
  - Group letters
  - Calls
  - Require Administrator to answer questions
- Review final rules

Opportunities to Get Involved in 2017

Reimbursement Rulemaking

- Inpatient payment policy
  - Pre-Proposed Rule: early 2017
  - Proposed Rule: April 2017
  - Comment: April – June 2017
  - Final Rule: August 2017
- May seek Congressional intervention
  - Educate Members: ongoing in 2017

Coverage Determination

- Will likely request modify process
- Need support from TC that modified process critically important

How You Can Help

Check Reimbursement website for calls to action

Review the issue

Submit your comment

****If no one comments CMS assumes everything is working fine**

Act Now: Comment on the CMS Proposed Outpatient Payment Rule

The Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2017 OPPS proposed rule on July 6. We applaud CMS for taking this important first step forward in improving the outpatient payment rate for hematopoietic cell transplantation (HCT). The proposed changes are the result of many conversations with CMS, as well as past comment letters from transplant centers across the country and represent a sustainable future for outpatient HCT.

While the proposed rule is an important step forward, the details matter and there are some important modifications the NMDP/Be The Match will be requesting to make sure that the new outpatient payment rate is set using the best data possible and can be updated over time as costs naturally fluctuate.

The proposed changes will substantially change payment and rate setting for Medicare outpatient HCT. We ask that you submit a comment letter thanking the CMS for including these changes in the proposed rule and recommend that CMS re-calculate the proposed C-APC rate using only the CPT code 38240 claims that include revenue code 0819. CMS takes comments from the transplant centers very seriously and will consider the changes you recommend as they finalize the OPPS rule.

Please Submit a Comment to CMS on Behalf of Your Transplant Program

Comments are due to CMS by **September 6, 2016**. You can submit a comment as an individual health care professional and/or from your transplant center. To assist in this process, we've drafted a comment letter you can quickly customize and send. Access letter. Read NMDP/ASBMT's joint comments to CMS on the CY17 OPPS Proposed Rule (PDF).

If you would like to talk through the OPPS proposed rule analysis and learn more about how you can comment, please contact Alicia Silver at alicia.silver@nmdp.org or 763-406-8669 to set up a quick conference call with our team.

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Questions?

https://network.bethematchclinical.org/transplant-centers/access-to-transplant/reimbursement-support/

Contact Alicia Silver for more information

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763-406-8669