Webinar PACT Act/Section 108 Implementation Specifics from the FY 2021 IPPS Final Rule

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Welcome

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Thank you!!


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MEDICAL UNIVERSITY of SOUTH CAROLINA

Today's Speakers

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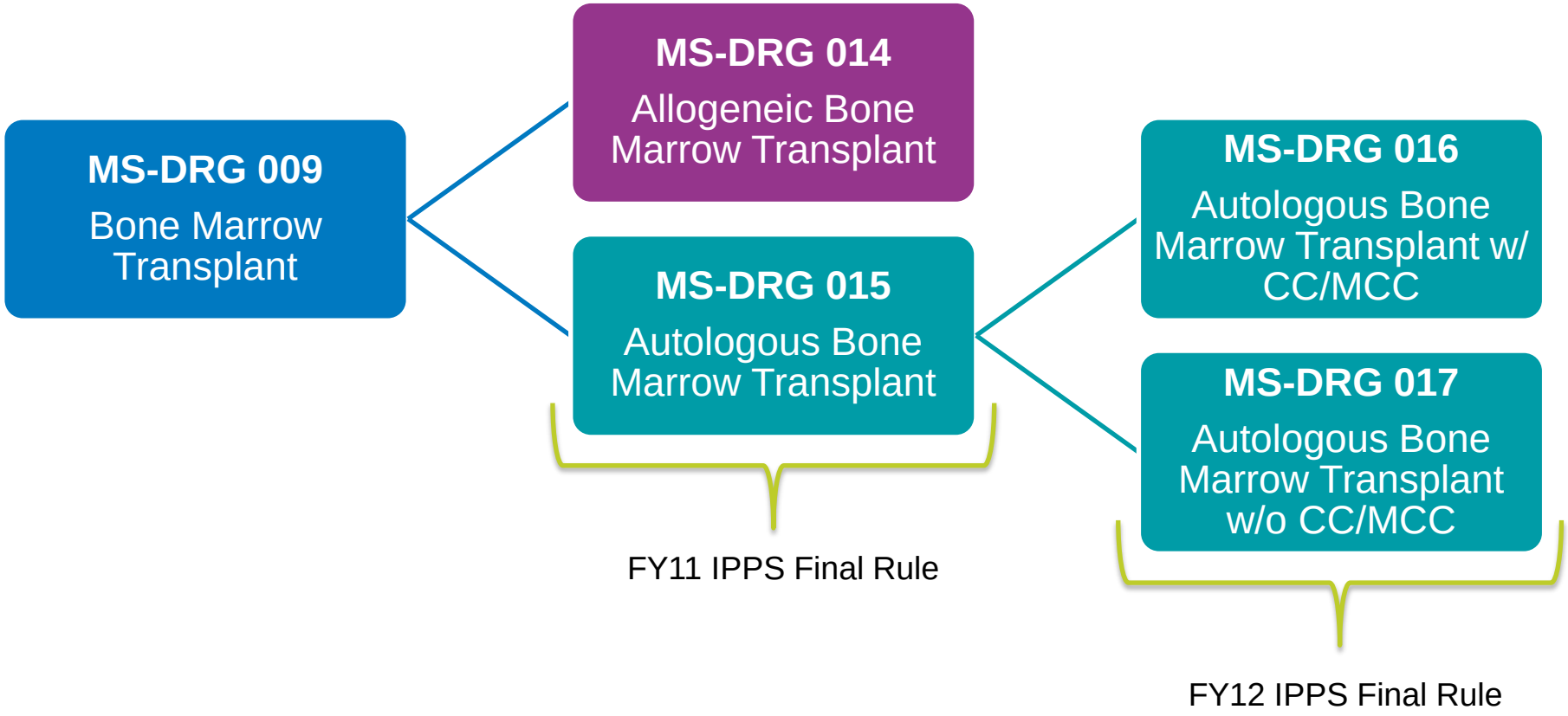
Agenda

- Brief Primer and Overview of the Inpatient Prospective Payment System (IPPS)
- Improved Medicare Inpatient Reimbursement for Allogeneic Stem Cell Transplant
  - The Backstory and passage of the PACT Act! (aka Section 108)
- FY 2021 Medicare Inpatient Payment Final Rule
  - Stem cell transplant payment updates
  - CAR-T updates
- Section 108 Implementation
  - Understanding what CMS finalized
  - Preparing for section 108 cost reimbursement
  - Next steps
- Discussion and Q/A

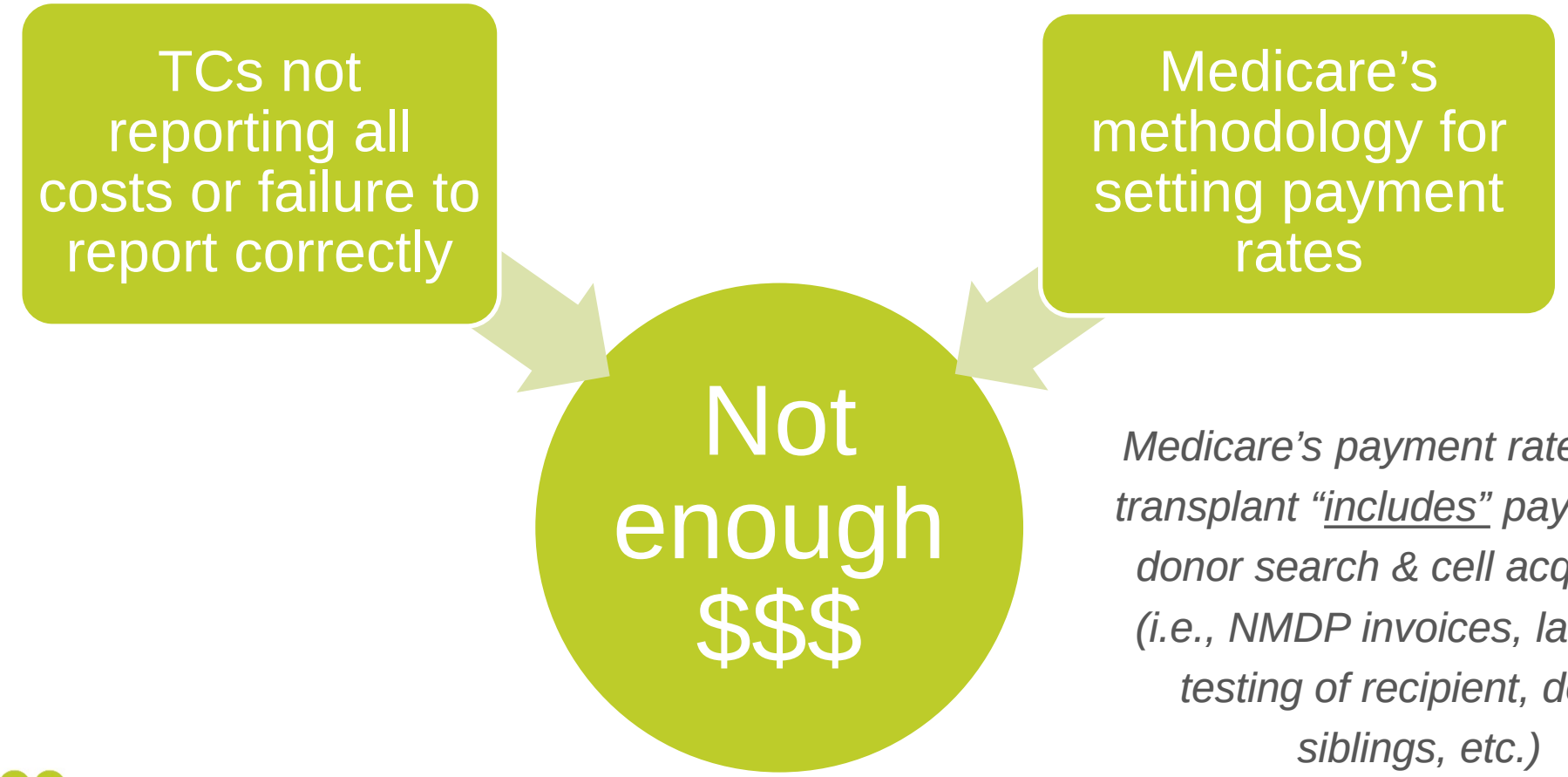
Quick Primer About the Medicare Inpatient Prospective Payment System (IPPS)

- Impacts Medicare payment to hospitals for their inpatients
  - Payment made through groups called Medicare Severity Adjusted Diagnosis Related Groups (MS-DRGs). Note the earlier version of this payment method was simply called Diagnosis Related Groups (DRGs)
  - Single set of national prices created that are adjusted for each hospital depending on geographic location and other hospital-specific factors such as teaching hospital status, and their share of uncompensated care
  - Additional payments may be added to hospital's adjusted base payment if warranted by the type of case (new technology eligible case) and extraordinary high case cost as estimated by Medicare in excess of payment received
  - A single MS-DRG payment is made per hospital discharge
- Payments and other changes are proposed and finalized annually

History of Medicare Bone Marrow Transplant Payment Groups Called MS-DRGs



Despite Increases Over Time, Medicare Reimbursement Still Inadequate for Allogeneic Stem Cell Transplant



Medicare's payment rate for allo transplant "includes" payment for donor search & cell acquisition (i.e., NMDP invoices, labs/HLA testing of recipient, donor, siblings, etc.)

Problems: Low Payment and Patient Access

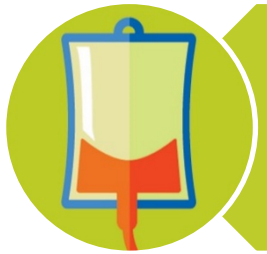
- Transplant centers incurring losses on vast majority if not all Medicare allogeneic transplants
- Magnitude and year-over-year continued losses unsustainable; threatening future access for Medicare beneficiaries
- Lots of data analysis and discussions with Medicare payment policy staff pointed to seeking a policy solution that necessitated Congress changing the law

Legislation Introduced Called The Patient Access to Cellular Transplant (PACT) Act

- Need legislation that requires Medicare to reimburse for donor search and cell acquisition costs on a reasonable cost basis, separate from the MS-DRG payment

- PACT act first introduced in 2018 and then again in May 2019

Transplant centers lose thousands of dollars on each Medicare beneficiary they treat primarily due to Medicare's flawed methodology of accounting for true costs associated with donor search and cell acquisition



The financial losses transplant centers face are unsustainable and threaten patient access

The PACT Act will require donor search and cell acquisition costs be reimbursed separately and at a reasonable cost rate — similar to solid organ thus significantly improving reimbursement

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Success!

- PACT Act language included in the Further Consolidations Appropriations Act (FCAA) of 2019 as Section 108
- Signed into law on Dec. 20, 2019
- Bottom Line:
  - CMS to develop a separate cost-based reimbursement methodology to pay for donor search and cell acquisition costs beginning with hospital cost reporting periods on or after 10/1/2020

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NEXT STOP…MEDICARE'S INPATIENT PROSPECTIVE PAYMENT SYSTEM FINAL RULE

BETTER REIMBURSEMENT ON ITS WAY FOR ALLOGENEIC STEM CELL TRANSPLANT AND CAR-T

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Specifics of the FFY 2021 IPPS Final Rule

Timeline

- Proposed rule: released May 11, 2020 (very late)
- Final rule: released Sept 2nd
- Phased Implementation beginning Oct 1st

Importance of this rule to Transplant Centers and our focus for today

- CAR-T payment updates and other updates and payment changes that your transplant center will want to review
- Section 108 implementation specifics outlined in the final rule with direct responses to questions raised by the NMDP and the public

Highlights of Final Rule CAR-T Changes

- Current NTAP for Kymriah and Yescarta expires starting FY 2021
- CAR-T cases assigned to new MS-DRG 018 with a national unadjusted payment rate of about $240,000
  - Starting Oct 1, 2020, CAR-T cases identified as having no product cost will be paid at a reduced amount (17% of the $240,000) since CMS set aside certain CAR-T cases in developing the payment rate for MS-DRG 018
  - CMS has not yet released information on how it will flag the cases to pay at a reduced amount, but broadly these are clinical trial cases (where the CAR-T is under study and not something else) and expanded access use cases
- New diagnosis codes for cytokine release syndrome effective Oct 1, 2020 and clarification released by CMS on how to code CRS as a complication with a specific T-code so that cases are assigned into MS-DRGs 814-816 when CRS occurs separately from the claim with the CAR-T procedure
- No NTAP requests finalized for two new CAR-T products since neither was FDA approved by July 1st
- Two new ICD-10-PCS codes were finalized for implementation starting Oct 1st for the latest CAR-T products; they are in a separate coding table (XW2 rather than XW0) so be sure your coders know this

Additional Information on CAR-T for FY 2021

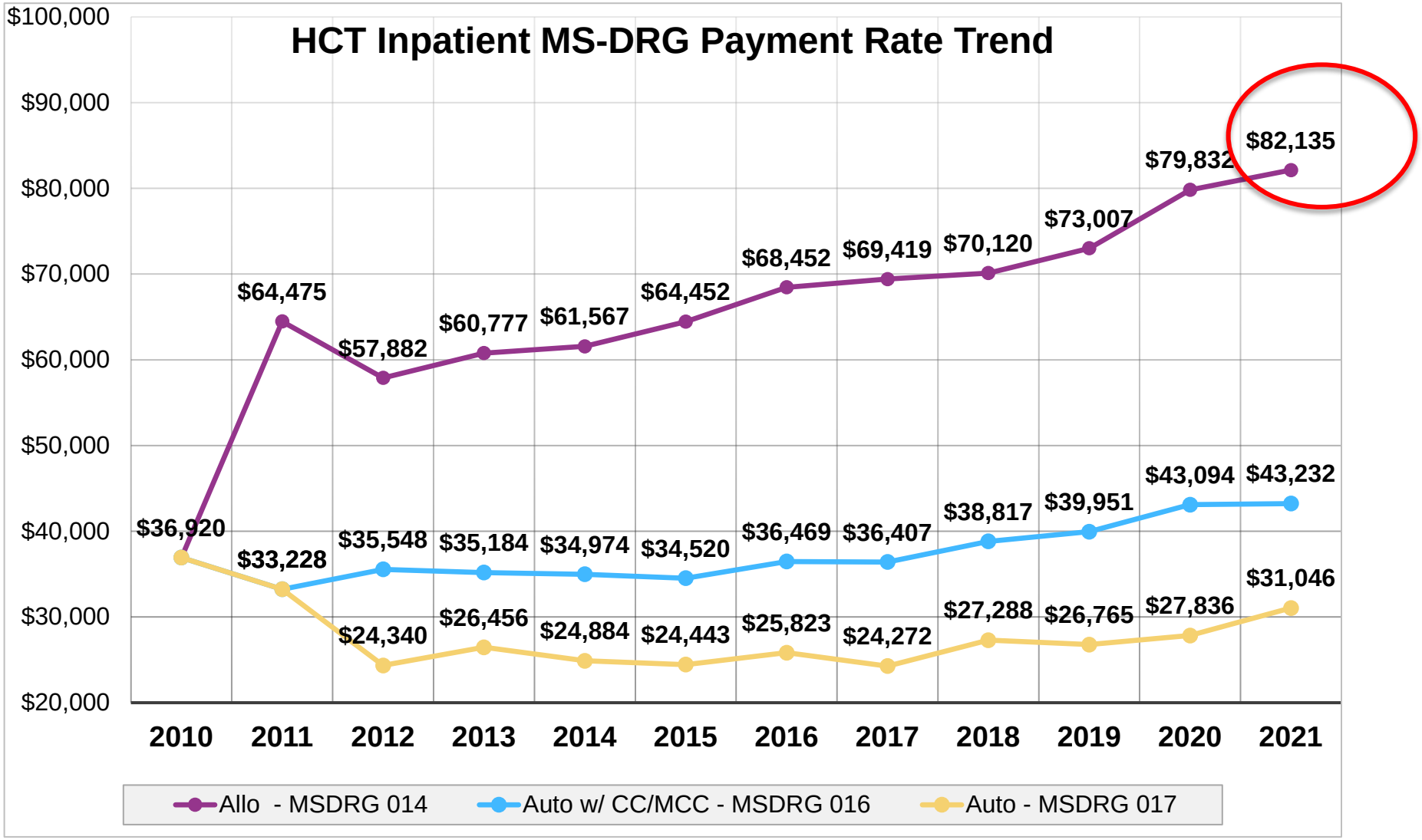
- CMS responded to commenters who raised concerns about the problems with the relative weight methodology for MS-DRG 018 due to inconsistent hospital charging practices by stating, *"With respect to the concern about hospital charging practices, we reiterate our earlier response that there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs."*
  - This confirms what we've been telling transplant centers for years about setting their charges appropriately
- Estimate CAR-T payment for your institution for FY 2021 by doing the following:
  - Find your CAR-T product charge on your institutional chargemaster
  - Determine if it needs updating. What is your typical drug pricing methodology? Share the above CMS quote
  - Given finance your average total charge for your CAR-T cases from last year and have them use your operating CCR, geographic adjustment factor, wage index, IME, DSH and ask them to compute what the payment to your institution would be

Highlights of the Final Rule Changes for Stem Cell Transplant MS-DRGs

- Still only 3 MS-DRGs for stem cell transplant
  - MS-DRG 014: Allogeneic Stem Cell Transplant
  - MS-DRG 016: Autologous Bone Marrow Transplant w/ CC/MCC (name reverts to this now that CAR-T cases have their own MS-DRG)
  - MS-DRG 017: Autologous Bone Marrow Transplant w/o CC/MCC
- Payment rates updated and all are higher than current rates but still not sufficient for MS-DRG 014 which is why the passage of Section 108 in the PACT Act matters so much

Payment increasing for MS-DRG 014 but still insufficient

FY 2021 Final Rule Payment Rates for Stem Cell Transplant MS-DRGs



PREPARING FOR SECTION 108 COST REIMBURSEMENT

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At a Glance: Steps to Cost-based Reimbursement

Effective date: Cost reporting periods beginning on or after October 1, 2020

No change to the definition of donor search and cell acquisition

Yippee!! CMS listened to commenters and will allow actual charges to be reported (as is done today) for allogeneic HCTs

Hospitals will have to maintain itemized statements that identify all services furnished, the charges, person/donor receiving the service, and the recipient's health care insurance number

Interim payments defined by CMS in response to comments and will occur on a bi-weekly basis

Cost reporting changes - new instructions forthcoming through separate rulemaking

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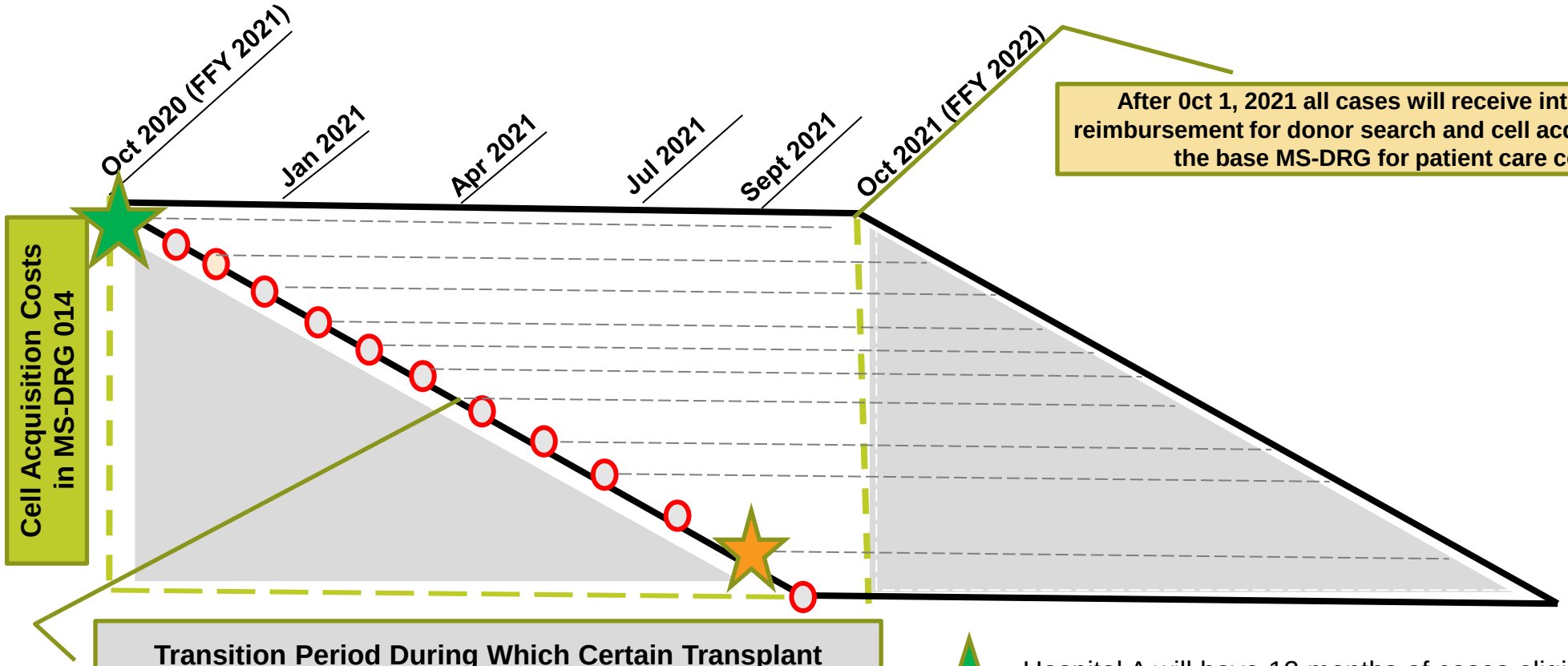
Specifics Finalized for FY 2021

- Section 108 only applicable to subsection (d) hospitals (i.e., PPS hospitals) for inpatient cases and the implementation is budget neutral

- Interim payments will start being made to these hospitals for discharges after the start of their cost period beginning on or after 10/1/2020
  - MS-DRG 014 payment on a per case basis as today
  - Additional bi-weekly interim pass-through payment will be made
  - Reconciliation of the interim payments against actual acquisition cost will occur at cost report settlement
  - Section 108 will get phased-in during FFY 2021 since hospitals do not have the same cost reporting period which means not all inpatient allogeneic stem cell transplant cases during FFY 2021 will be eligible for reasonable cost reimbursement
    - For example, hospitals with cost reporting periods coinciding with the FFY of 10/1/2020 – 9/30/2021 will be 1st to receive cost reimbursement and will receive it for 100% of their discharges
    - Hospitals with a cost reporting period starting on 9/1/2021 will be the last to receive cost reimbursement and will only see it for 1 month of their discharges in this period

Visual Representation of Phased-In Implementation



Hospital A will have 12 months of cases eligible for cost reimbursement at settlement

Hospital B will be paid for cell acquisition through MS-DRG 014 for 11 months and will have only 1 month of cases eligible for cost reimbursement at settlement

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More Section 108 Specifics

- Definition of Donor Acquisition Charges – Medicare proposes to keep the same definition as exists today*
  - National Marrow Donor Program fees, if applicable, for stem cells from an unrelated donor
  - Tissue typing of donor and recipient
  - Donor evaluation
  - Physician pre-procedure donor evaluation services
  - Costs associated with harvesting procedure (e.g., general routine and special care services, procedure/operating room & other ancillary services, apheresis services, etc.)
  - Post-operative/post-procedure evaluation of donor
  - Preparation and processing of stem cells

* in Publication 100-04, Chapter 3, Section 90.3.3.A and Ch. 4 Section 231.11

Hospital Reporting Specifics from the Final Rule

- The NMDP and its network of transplant centers had a lot to say to CMS about the agency's proposal to require hospitals to change their current practice of reporting actual charges to reporting a standard acquisition charge for **all** allogeneic transplants

> Comment: The majority of commenters disagreed with our proposal to require a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to formulate a standard acquisition charge (SAC), as reflected in proposed new paragraph 42 CFR 412.113(e)(3).

- The great news is that CMS listened and did not finalize its proposal!
- Transplant providers will continue reporting actual donor charges as is the current rule!

Additional Quotes from CMS

Several commenters stated that resources and costs associated with acquiring hematopoietic stem cells for an allogeneic hematopoietic stem cell transplant vary significantly among the different types of donor search and stem cell acquisition services (for example, related, unrelated, cord blood, haploidentical, etc.). Commenters suggested that we consider requiring providers to formulate multiple SACs based on the different type of donor search and stem cell acquisition as they stated this more accurately aligns different costs with the charges associated with the types of acquisition. A commenter also expressed concern that requiring an average charge is another form of "cost compression."

These commenters suggested that the proposed requirement, if finalized, would require a hospital to renegotiate its contracts among all payers, which would be administratively burdensome and potentially impact hospital reimbursement. A few commenters noted that although the proposed methodology requires Medicare to reconcile the SAC with actual charges at the end of the cost reporting period, commercial payers would be impacted by this approach because no settlement opportunity exists for them.

Review: Billing of Actual Donor Charges

- Medicare requires actual donor charges to be held and billed under revenue code 0815 on the recipient's transplant claim per CMS Claims Processing Manual, Chapter 3, Section 90.3.1
  - Note that this may be several statements for related donors until a match or even if a match cannot be made and cells must be purchased from NMDP – all actual charges summed should be reported on the recipient's bill
- Many commercial payers allow real-time billing of actual donor charges under the recipient's name and do not require hospitals to hold charges until the transplant claim as Medicare/government payers do
  - New NUBC codes went live July 1st which facilitate real-time billing of donor services

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New NUBC Codes – Effective July 1, 2020

See the Appendix for Examples of Use

- **Condition code 88:** allogeneic HSCT related donor charges. This code is used on a claim submitted solely for separately billed charges for evaluating the suitability of HSCT donors, prior to the submission of the actual inpatient transplant claim.
- **Value code 88:** This value code indicates the number of related donors evaluated and is reported on the recipient's transplant claim. A zero is allowed for no related donors evaluated.
- **Value code 89:** this code is used to report the total charge amount for both related and unrelated donor services, including charges that were submitted on separate claims. This code would be reported on the recipient's transplant claim.
  - Value codes are optional per payer requirements, but reporting is encouraged because it provides more complete information about the transplant and helps to ensure accurate reporting

Interim Payments to Be Made Using Historical Data During the Phase In Year

- In the final rule CMS clarified what it means by “interim pass-through” payments
  - Payments are not “claims-driven” but instead a pre-computed bi-weekly payment
  - The bi-weekly payment will be computed using historical data from the PS&R revenue code 0815 charges reduced to cost using the hospital’s cost to charge ratio divided by 26 to calculate the bi-weekly payment amount
  - The bi-weekly payment is an estimated payment which means providers can work with their MACs to update the estimates on a quarterly basis

Expected Impact to Transplant Centers

- Significant improvement in Medicare reimbursement
  - Being phased-in during FY 2021 so the benefit to each transplant center will be variable
  - Starting 10/1/2021, *all* inpatient allogeneic cases will be eligible for reasonable cost reimbursement

BUT

Work will be required on the part of transplant centers to ensure all related and unrelated donor search and cell acquisition charges are captured and reported properly!!

NEXT STEPS FOR ALLOGENEIC STEM CELL TRANSPLANT PAYMENT POLICY

Accuracy of Claims and Expense is Essential

- To achieve complete and accurate cost-based reimbursement correct coding and charge capture on claims and capture of expenses in the cost report while retaining documentation for audit are vital
- There are things that transplant centers can already be doing
- Let's start with claims….and then discuss cost reporting

Reminder of HIPAA Transaction Sets

- Chapter 24 of the Medicare Claims Processing Manual, Section 20, "…Medicare FFS is required, as are all payers in the US, to adopt the standards specified under HIPAA."
  - NUBC is the designated standards organization for institutional (e.g., hospital) claims

It's the Law

Health care providers, health plans, payers, and other HIPAA-covered entities must comply with Administrative Simplification.

The **requirements apply to all providers who conduct electronic transactions**, not just providers who accept Medicare or Medicaid.

Reporting Revenue Code 0815

- **Revenue Code 0815 defined by NUBC for reporting HSCT donor charges on all claims – both related and unrelated donor charges**
- Revenue Code 0815 requires CPT/HCPCS code on outpatient claims
- https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9674.pdf

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.

Question: What Happens if My Center Hasn't Been Using Revenue Code 0815?

- Prior to section 108, payment for donor search and cell acquisition was made through MS-DRG 014 and did not rely upon correct revenue coding or charge capture
- Going forward, transplant centers will not receive correct payment unless revenue code 0815 is properly reported.
  - Have your Center's reimbursement manager run a PS&R report for your 2019 fiscal year
    - If revenue code 0815 charges for cell acquisition is not on the PS&R, then you will need to contact your MAC to determine if/how an estimated interim payment will be made
    - Additionally, consider submitting adjustment claims to properly report 0815
- Don't forget to also capture and report **ALL** related donor charges in addition to the unrelated cell acquisition charges in revenue code 0815 to avoid underpayment!

Vital for the Cost Report

- Related and unrelated stem cell acquisition charges for all cases/all payers (i.e., total revenue billed under revenue code 0815) should be reported correctly on the cost report as this impacts the cost-to-charge ratio (CCR) calculation used in cost settlement.
- For expenses, best practices include:
  - Assign expense associated with purchased donor services to a unique General Ledger (GL) sub-account
  - Create a unique cost center for staff/services that solely support donor services
- Report all direct donor expense (purchased services and staff) using **cost center 77** in the Medicare cost report.

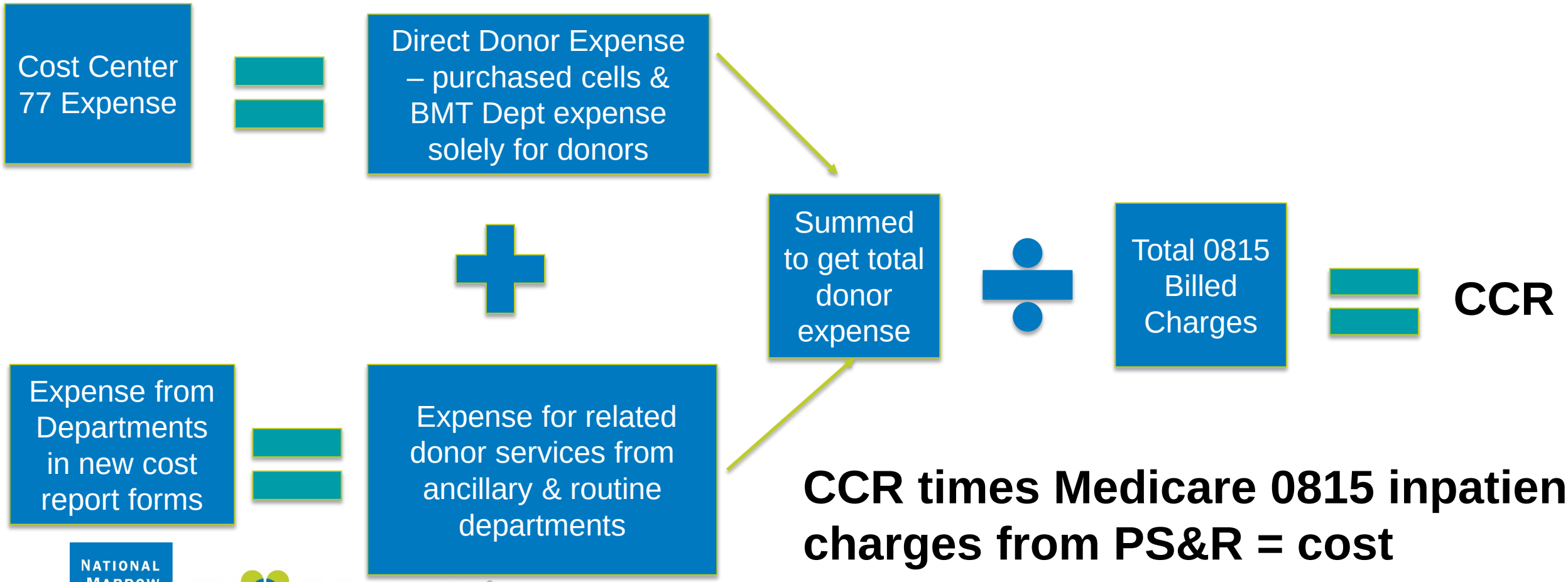
Question: What Happens if My Center Hasn't Begun Using Cost Center 77?

- Previously, there was no edit or audit mandate to ensure transplant centers migrated over to using cost center 77
- Going forward, transplant centers will not receive cost-based reimbursement unless expense and revenue are properly reported in the cost report – including in cost center 77
  - Actual donor search and cell acquisition for all patients needs to be captured in cost center 77 for all purchased services/actual donor expense
  - New cost report forms forthcoming to calculate expense of services furnished to related donors.
  - CMS will compute a cost-to-charge ratio = expense in CC77 plus calculated expense divided by 0815 revenue for all allogeneic stem cell transplant cases
  - CMS will calculate Medicare's actual cost using charges billed under revenue code 0815 on Medicare discharges multiplied by the CCR and will compare this to total interim payment and reconcile differences

Still Awaiting Specific Cost Reporting Instructions from CMS

- CMS has stated that it will release additional instructions on how providers are to report costs associated with the allogeneic donor search and cell acquisition costs, particularly related donor costs in departments other than the transplant department
- CMS will modify cost reporting forms and instructions using solid organ worksheets as a model
- Cost reporting will allow providers to capture costs related to purchased services/cells and also compute the costs for different departments' services to related donors to be summed for a capture of total allowed expenses. These expenses will be compared to total revenue billed under 0815 for the services
- Once the forms and instructions are released, your transplant center's cost reporting manager will want to review and submit comments/notify NMDP etc. if things are unclear

New Cost Reporting Instructions to Calculate Total Donor Costs



CCR times Medicare 0815 inpatient charges from PS&R = cost

TCs “To Do’s”: Things to Review with Finance ASAP!

- Do you used revenue code 0815 on all HCST donor services?
- Do you use standard cost center (line 77) for “Allogeneic Stem Cell Acquisition”?
- Do you report all related & unrelated stem cell acquisition charges on the cost report?
- Do you have a unique General Ledger (GL) sub-account established for purchased donor services to facilitate matching of donor expenses and revenue?
- Do you have a process for retaining invoices and receipts for all related donor services and all cell acquisition costs so they are easily accessible for audit?
- Do you have a documented system to retain itemized department charges for related donor services?

Discussions/Q&A

Thank you!

APPENDIX A

Reporting New NUBC Codes

Type of Hospital Donor Services	Medicare	Medicaid & Commercial – Per Payer Requirement/Agreement
Related donor(s) services (e.g., evaluation, testing, cell collection, cell processing)	Held and reported on recipient transplant claim using revenue code 0815	**Option 1** = Held and reported on recipient transplant claim using revenue code 0815 or **Option 2** = billed on separate claim under recipient name using revenue code 0815, specific CPT/HCPCS codes, **and condition code 88**
Unrelated donor services (e.g., NMDP search, testing, cell purchase, cell processing)	Held and reported on recipient transplant claim using revenue code 0815	**Option 1** = Held and reported on recipient transplant claim using revenue code 0815 or **Option 2** = billed on separate claim under recipient name using revenue code 0815, specific CPT/HCPCS including 38204, **and condition code 88**

Reporting New NUBC Codes (Cont.)

Transplant Recipient Claim	Medicare	Medicaid & Commercial – Per Payer Requirement/Agreement
Recipient Services (e.g., conditioning prior to SCT and hospital services to transplant and monitor patient (e.g., room charges, ICU, lab, imaging, drugs, etc.)	All previously held donor claims with cost of services summed and reported under revenue code 0815. Use 38204 if outpatient transplant. Value code 88 = Number of related donors evaluated; zero is acceptable for none Value code 89 = total charges for all related and/or unrelated donor charges. Should equal charges on revenue code 0815 line	If held, donor services reported under revenue code 0815 Value code 88 = Number of related donors evaluated; zero is acceptable for none Value code 89 = total charges for all related and/or unrelated donor charges including those reported on separate claims plus that reported with revenue code 0815 on recipient claim, if any