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Emerging Issues in Provider Based Determinations and Appeals

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Goals for Today…

- Background to Medicare's Provider-Based (PB)
- Update on enforcement activities in PB space
- Tackling PB denials
- *If time allows*, review the proposed payment changes impacting PB facilities from the CY 2019 HOPPS Proposed Rule

Quick Background to Provider-Based Rules

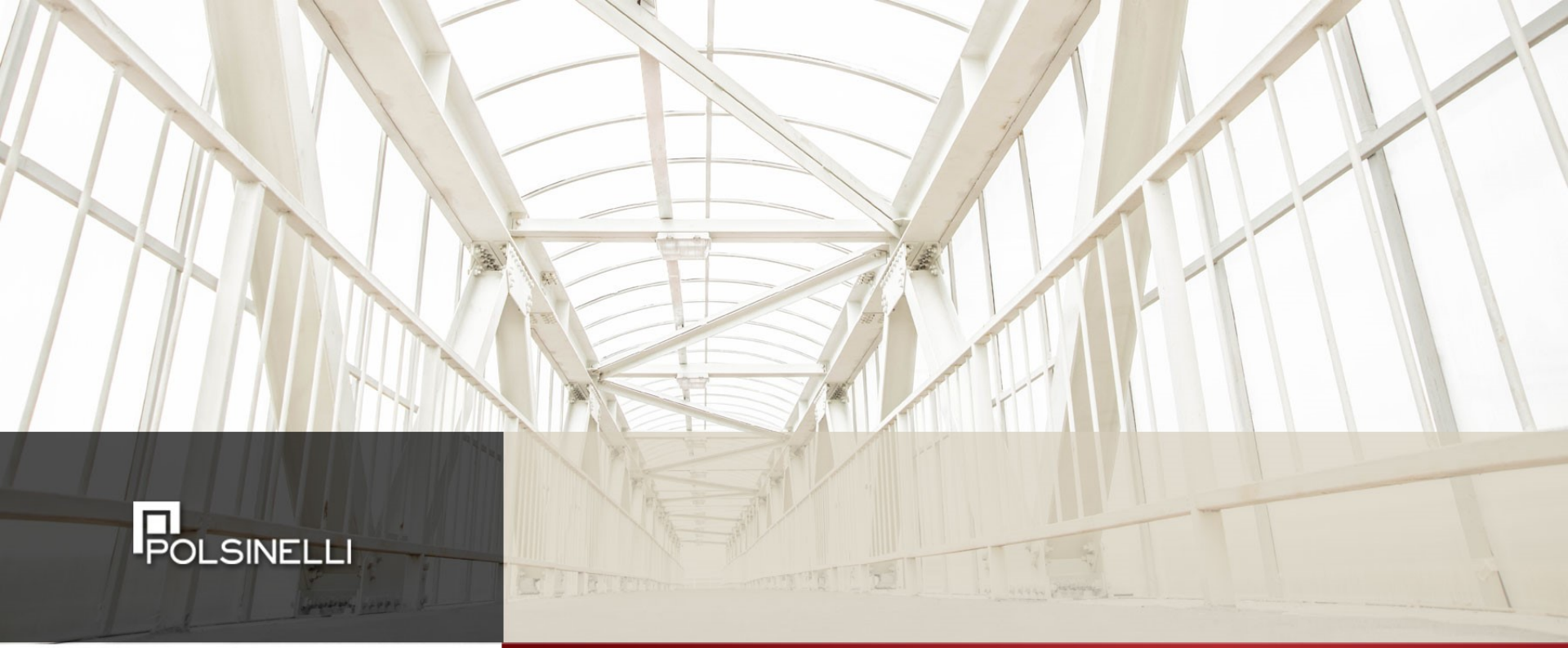
- Provider-based requirements:
  - Provider-based rules are found at 42 CFR 413.65
    - Require facilities to be clinically, administratively and financially integrated with a “main provider”
    - Submission of an attestation is voluntary
  - Provider-based payment rules were developed following Sect. 603 of the Bi-Partisan Budget Act of 2015
    - Modified payment rules for provider-based facilities

Updates from the Provider-Based World

- CMS continues to its enforcement platform against "non-compliant" hospital outpatient departments (HOPDs)
- Some areas of enforcement we continue to see active:
    - Space-sharing arrangements
    - Time sharing arrangements
    - Naming requirements.
- CMS continues to indicate future guidance regarding space-sharing and other provider-based issues is imminent, but it has yet to get released…

Updates from the Provider-Based World

- CMS is pushing policy interpretation out to the CMS Regional Offices (ROs)
- Encouraging utilization of those ROs for guidance regarding interpretation of the provider-based rules
- CMS Central Office seems to be stepping out of policy guidance and interpretation
- CMS released CY2019 HOPPS Proposed Rule with 4 new payment policy proposals aimed at reducing incentives for slowing expansion of off-campus HOPDs



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MY PROVIDER-BASED ATTESTATION JUST GOT DENIED, NOW WHAT?

Provider-Based Denial Timeline

- Upon receipt of a denial, three timelines to be concerned with immediately – 30 days, 60 days, and 90 days:
  - **30 days**: Notification of intent to CMS RO – 3 options:
    1. Notify CMS RO that you intend to make the changes necessary for the facility to comply with provider-based rules
    2. Notify CMS RO that you will forgo provider-based status and seek to enroll the facility as a freestanding provider or supplier of services.
    3. Do nothing

  NO opportunity for extensions, or at least we've not seen CMS indicate any willingness to extend

Provider-Based Denial Timeline

- **60 days**: filing deadline for "Request for Reconsideration"
  - CMS ROs willing to extend, but likely factually dependent and likely variable by region.
- **90 days**: Submission of "complete request" or "complete enrollment application"
  - NO opportunity for extensions, or at least we've not seen CMS indicate any willingness to extend
- ***6 months***: time through which CMS will continue to make payments at a *freestanding* rate
  - NO opportunity for extensions, or at least we've not seen CMS indicate any willingness to extend

Provider-Based Denial Timeline

30 days, Option 1

- Notify CMS RO that you intend to make the changes necessary for the facility to comply with provider-based rules
  - CMS will continue to reimburse the facility at the *freestanding* rate for up to 6 months.
  - Provided, a "complete request" for a determination of provider-based status is submitted to CMS within 90 days.
  - Have up to 6 months to complete modifications, updates, etc., to coming into compliance with PB rules.

Provider-Based Denial Timeline

30 Days, Option 2

- Notify CMS RO that you intend that you will seek to enroll the facility as a freestanding entity and meet the requirements to qualify.
  - Could be an ASC, physician practice, IDTF, or other facility depending on the underlying services.
- As with seeking PB status, CMS will continue to reimburse the facility at the freestanding rate for up to six months
- Provided, a “complete enrollment application” is submitted within 90 days.

Provider-Based Denial Timeline

30 Days, Option 3

- Don't respond at all
  - If you fail to respond to CMS' denial – even fail to do so timely…
  - All payments end 30 days following the denial notice.
  - Would suggest notifying if intent is to simply close the facility down – avoid other enrollment complications

Provider-Based Denial Timeline

60 days

- Filing deadline for “Request for Reconsideration” (RFR)
  - Begins first level of appeal process
  - Odd place to be legally and operationally because the RFR formally challenges CMS’s denial and disagrees with it, legally and/or factually
  - While the Notification of Intent (already filed) requires you to essentially concedes to CMS’s findings

Provider-Based Denial Timeline

60 Days Continued

- If you pursue provider-based status you have to come into compliance with the very determinations you seek to challenge on appeal
- If you pursue separate enrollment, you essentially concede to those findings and pursue a different path
- RFR must include the issues or finding of fact with which you disagree, and why.
- Maybe an opportunity to extend deadline, even outside normal “good cause” exceptions.

Provider-Based Denial Timeline

90 days, Option 1

- Submission of a "complete request" for a determination of PB status
- Not just a new attestation
- *In practice*, we have seen a variety of expectations among different ROs
  - New attestation
  - Updates to existing attestations
  - Attestation, plus other materials, e.g., floor plans, construction documents, space leases, etc.

Provider-Based Denial Timeline

90 days, Option 2

- Submission of a "complete enrollment application"
  - Would clearly include a CMS Form 855A or 855B
  - Submitted to the MAC – likely a copy to CMS RO to evidence it was filed and facilitate processing – given 6 month back end window.
  - Would likely include passing a survey, where required – e.g., ASC or IDTF
  - Failure to provide the information, or sufficient information, will lead to termination of the facility and cessation of payments

Decisions, decisions, decisions…

- Only 30 days to decide from the date of denial. Lots to decide quickly….
  - *Coming into compliance*:
    - What is feasible in light of the denial?
    - Turns, in part, on the nature of the denial

Decisions, decisions, decisions…

- Examples from different types of denials:
  - Space-sharing?
    - Might require relocation, construction, re-negotiation of contracts.
    - Other space-sharing restrictions to consider? (e.g., ASC or IDTF).
  - Naming? Might require new signage, new advertising.
  - On-campus denial? Might require submission of attestation as off-campus facility, meeting additional requirements, relocation, etc.

Decisions, decisions, decisions…

- If construction or relocation will be required,
  - Can it be completed in a timely fashion?
  - Will it be cost prohibitive?
  - Will CMS RO agree in advance to beginning construction or relocation?
- REMEMBER, you only have 6 months from the date of the denial to continue payments at the freestanding rate.
- So, construction or up fit timelines will matter

Decisions, decisions, decisions…

- What about billing for services post-denial?
- You can continue to bill, but how?
- CMS does not offer much guidance, but is obligated to pay you at a freestanding rate
- No known modifier to flag claims for payment for a denial
  - Could inquire to CMS RO issuing denial.
- Using PO vs. PN modifier
  - Could turn on strength of your underlying facts, appeal posture and risk tolerance
- Could face refunding if CMS pays too much, and you lose your RFR

Decisions, decisions, decisions…

- Other reimbursement impacts
  - 340B status and payments
    - Possibly less of an issue today in light of CY2019 HOPPS proposals
    - Reducing payment for non-excepted PB HOPDs
  - Excepted vs. non-excepted status

Recouped Payments

- Denial of provider-based status requires CMS to recoup payments for the period of denial.
- From date of denial backwards to the first day billed as provide-based
- Length of recoupment depends on whether an attestation was submitted, submitted and denied, not submitted

Recouped Payments

Attestation submitted, but denied:

- CMS recovers difference between the amount of payments actually made to the facility and the amount CMS estimates should have been paid
- Extends back only to the date the complete attestation was submitted.
- No guidance regarding attestations submitted a year or more after services are provided, and whether CMS would assert recoupment against that prior time period.
- Based on current experience, answer would appear to be YES.

Recouped Payments

Attestation submitted and approved:

- Depends on whether any “material changes” occurred and whether CMS was notified
- “Material change” has not been specifically defined
- Examples include, but are not limited to, changes in ownership, entry into a new or different management contract, changes in location, or changes in licensure status

Recouped Payments

- *Notice of material change furnished*:
  - PB status ceases on the date CMS determines the facility no longer qualifies as PB, and $$ recouped back to that date
- *No notice of material change furnished*:
  - PB facility treated as though no attestation was submitted, and $$ recouped for all cost reporting periods subject to reopening

Recouped Payments

- *No attestation submitted*:
  - CMS will take the following actions
    - Notify provider of denial and specific compliance failures
    - Review past cost-reporting periods, and
    - Recover the difference between the amount of payments made to the facility and the amount CMS estimates should have been paid.
  - This review extends to all cost reporting periods subject to reopening
  - In theory a longer window from which to recoup

Ready to File an Appeal?

- *Stage 1* – File RFR (recall, within 60 days of denial)
  - Follows the appeal process set forth at 42 CFR 498.22
- *Stage 2* – Appeal to an ALJ (within 60 days of reconsideration decision)
  - Appealing specific factual or legal issues.
- *Stage 3* – Appeal to Departmental Appeals Board
- *Stage 4* – Appeal to Federal Court
- Implications stemming from appeal backlogs?

Working Outside the Normal Appeals Process

- Determine whether CMS will resolve the denial outside the normal appeals process – possibly settle the matter
- Determine who at CMS to approach - the RO and/or the Central Office
- Consider whether to engage a lobbyist and/or politician, or even state and national hospital professional associations to aid in resolution of the matter.
- Always remember that provider-based compliance continues to be a top issue for CMS, so informally working out your dispute may be difficult – and will be highly factually dependent.

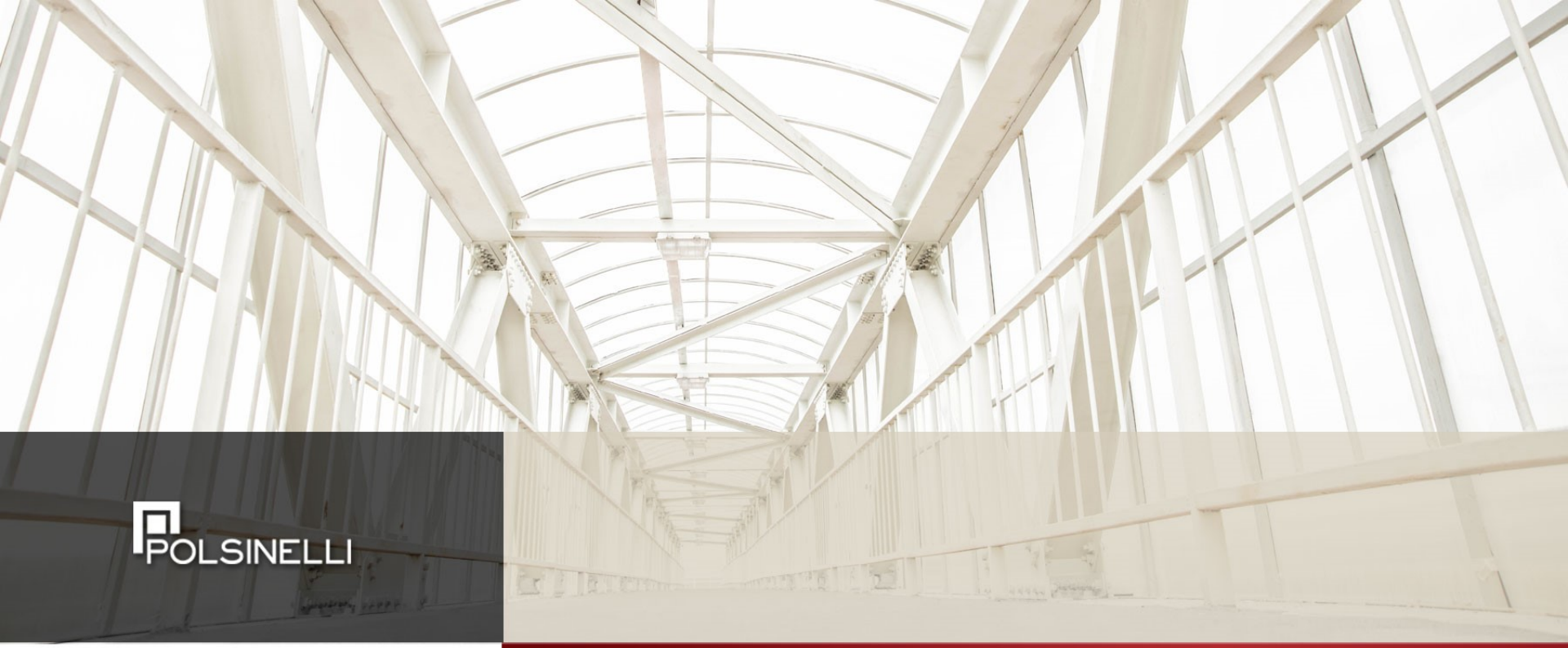
Settlement Prospects

- Is settlement possible?
  - Maybe, depends on the RO at issue – highly variable.
- Timing to raise?
  - Before or after filing of RFR? Depends….

Settlement Prospects

- If yes, what do you consider asking for?
  - Agreement on methodology for determining any overpayments and recoupments
    - Decide early on how to calculate recoupments and who will do it
    - CMS ROs are all over the map with regards to determining recoupments.
  - Agreement on any construction or other modification plans, including relocation.
  - Arguing for excepted status versus non-excepted status in connection with appeal?
    - You can try, but given current enforcement environment, likely a loser.

Questions?



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CY 2019 PROVIDER-BASED PAYMENT PROPOSALS

CY 2019 Provider-Based Proposals; In General

- New surprises contained in the Medicare CY 2019 OPPS Proposed Rule
  - Released on July 31, 2018
- Most important are 4 new proposals aimed specifically at payments for items and services furnished by off-campus HOPDs
- All impact payments under the Sect. 603 payment rules
- Comments due by 500PM EST, September 24, 2018

CY 2019 Provider-Based Proposals; In General

- **4 new proposals include the following**:
  1. Pay for separately payable Part B drugs acquired under the 340B program, and furnished from *non-excepted* off-campus HOPDs at amount equal to ASP – 22.5%.
  2. Inclusion of new modifier ("ER") on all items and services furnished by excepted off-campus "freestanding" hospital EDs.

CY 2019 Provider-Based Proposals; In General

- **4 new proposals include the following**:
  3. Limit payment for hospital "facility fees" (HCPCs GO463) with "PO" modifier to equivalent amount paid when billed with "PN" modifier.
  4. Limit expansion of services from *excepted* off-campus HOPDs to those contained in identified "clinical families of services" as measured from a base year between 11/1/14 – 11/1/15.

CY2019 Provider-Based Proposals; 340B Payment Policy

- Drugs provided in provider-based hospital outpatient departments ("HOPDs") formerly reimbursed at ASP+6%
- Effective 1/1/18, CMS implemented payment reductions / modifiers
  - *Payment* = ASP-22.5% when acquired under 340B
  - *Modifier JG* = 340B
  - *Modifier TB* = 340B but exempt from payment cut
- Non-exempted off-campus HOPDs exempt from 1/1/18 reduction; report TB (*and PN)* modifier

CY2019 Provider-Based Proposals; 340B Payment Policy

- **2018 OPPS Final Rule** - CMS issues payment reduction warning
  - *We will continue to monitor, the billing patterns of claims submitted by nonexcepted off-campus outpatient HOPDs as we continue to explore whether to pursue future rulemaking*
- CMS puts its PN (nonexcepted) modifier to work
- **2019 OPPS Proposed Rule** – CMS follows through on its warning
  - *CMS seeks to remove incentives for hospitals to shift drug administration services for 340B-acquired drugs to nonexcepted, off-campus HOPDs*

CY2019 Provider-Based Proposals; 340B Payment Policy

- 340B drugs provided by non-excepted, off-campus HOPDs reimbursed at:
  - ASP minus 22.5%; or
  - WAC minus 22.5% (when ASP unavailable); or
  - 69.46% of AWP (when WAC unavailable)
- Applies to separately payable, non-pass-through drugs (status indicator K)
- Continued focus on data collection to ensure payments don't vary based on site of service

CY2019 Provider-Based Proposals; 340B Payment Policy

- **Exempt Facilities**
  - CAHs (no modifiers required)
  - Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals (TB modifier required)
- **Exempt Drugs**
  - Pass-through drugs (status indicator G; TB modifier required)
  - Vaccines (status indicator F, L, M; no modifiers required)

CY 2019 Provider-Based Proposals; "ER" Modifier

- **Inclusion of "ER" Modifier**
  - What's being proposed?
    - Inclusion of ER modifier
    - On every claim line of UB-04
    - For hospital outpatient services
    - Furnished in an off-campus provider-based ED
  - ONLY CAHs exempted from requirement

CY 2019 Provider-Based Proposals; "ER Modifier"

- Why this new Proposal? At least per CMS:
  - CMS experiencing a "noticeable increase" in volume of off-campus ED visits under OPPS
  - Concern that hospitals shifting care from lower acuity settings (e.g., physician clinics and urgent care centers) to hospital Eds
    - Because of incentive for higher payments
    - Exemption from 603 payment reductions for *all* services furnished from an off-campus provider-based ED
  - MEDPAC proposal to include modifier to track services and volumes furnished in the off-campus provider-based ED setting

CY 2019 Provider-Based Proposals; "ER Modifier"

- Why this new Proposal? *Reading between the lines*….
  - CMS is gearing up to curtail the existing freestanding ED payment exception under 603
  - Today, hospitals can utilize the exception to bill non-emergent services under the exception and undermine intent of 603
  - ER modifier allows CMS to test this theory and if accurate, curtail the exception in the future

CY 2019 Provider-Based Proposals' Limit Payment for "Facility Fees"

- Limiting payment for "facility fees"
  - Payments for GO463 reported with PO modifier to be paid at amount equivalent with those reported with PN modifier.
  - Equalizes payment for excepted off-campus HOPDs to that for non-excepted off-campus HOPDs for this specific code.
  - Hospitals will continue to bill on UB-04 with PO modifier as always.
  - CMS will adjust the payment on the back end.
  - On-campus HOPDs continue to be exempt.

CY 2019 Provider-Based Proposals; Limit Payment for "Facility Fees"

- *Why*?
  - CMS indicates it is not seeing payment savings as anticipated.
  - CMS believes it is seeing continued growth in payments to excepted off-campus HOPDs.

CY 2019 Provider-Based Proposals; Clinical Family of Services

- **Return of the "Clinical Family of Services" for expansion of services from an excepted location**:
  - *Proposal*: CMS proposes to prohibit excepted off-campus HOPDs from billing for new services with a "PO modifier" unless the new service is within a clinical family of services that was previously provided by the HOPD from a baseline period measured from 11/1/14 through 11/1/15
  - List is furnished by CMS and contains the original 19 clinical families of services from the original proposed rule.

CY 2019 Provider-Based Proposals; Clinical Family of Services

37150 Federal Register / Vol. 83, No. 147 / Tuesday, July 31, 2018 / Proposed Rules

TABLE 32—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical families	APCs
Airway Endoscopy	5151–5155.
Blood Product Exchange	5241–5244.
Cardiac/Pulmonary Rehabilitation	5771; 5791.
Diagnostic/Screening Test and Related Procedures	5721–5724; 5731–5735; 5741–5743.
Drug Administration and Clinical Oncology	5691–5694.
Ear, Nose, Throat (ENT)	5161–5166.
General Surgery and Related Procedures	5051–5055; 5061; 5071–5073; 5091–5094; 5361–5362.
Gastrointestinal (GI)	5301–5303; 5311–5313; 5331; 5341.
Gynecology	5411–5416.
Major Imaging	5523–5525; 5571–5573; 5593–5594.
Minor Imaging	5521–5522; 5591–5592.
Musculoskeletal Surgery	5111–5116; 5101–5102.
Nervous System Procedures	5431–5432; 5441–5443; 5461–5464; 5471.
Ophthalmology	5481, 5491–5495; 5501–5504.
Pathology	5671–5674.
Radiation Oncology	5611–5613; 5621–5627; 5661.
Urology	5371–5377.
Vascular/Endovascular/Cardiovascular	5181–5184; 5191–5194; 5200; 5211–5213; 5221–5224; 5231–5232.
Visits and Related Services	5012; 5021–5025; 5031–5035; 5041; 5045; 5821–5823.

CY 2019 Provider-Based Proposals; Clinical Family of Services

- **Return of the "Clinical Family of Services" for expansion of services from an excepted location**:
  - If the new services are not included in the same "clinical family of services" and from the baseline year, then billed with "PN" modifier
  - *Proposal*: CMS also proposes to change the definition of "excepted items and services" found at 42 CFR 419.48

CY 2019 Provider-Based Proposals; Clinical Family of Services

- *Why the return*?
  - CMS indicates that hospitals are able to continue acquiring physician practices and merge them with existing excepted off-campus HOPDs and expand service offerings that are also considered excepted.
- CMS anticipates similar hospital/industry objections as under the original proposed rule
- CMS open to alternative suggestions and is soliciting comments, including utilization of MEDPAC's original recommendation of "capping" payments annually when compared to a baseline year.

CY 2019 Provider-Based Proposals; Clinical Family of Services

- *What if this proposal goes final*?
  - Proposed effective date: January 1, 2019
  - Need to determine all services billed from each specific excepted off-campus HOPD for the baseline year (tentatively 11/1/14-11/15
  - Compare to the services currently being billed
  - Determine what expansion possibilities exist and whether those services would be billed with a PO or PN modifier
  - Wait to see if CMS attempts to impose a retroactive impact, i.e., requires that claims provided and billed with a PO modifier prior to 1/1/19 be refunded in part when outside the "clinical family of services"

CY 2019 Provider-Based Proposals; Clinical Family of Services

- *Any exceptions*?
  - Yes, but narrow.
  - Any HOPDs approved through the mid-build process would have a baseline measured by the period beginning one year prior to the first date of service
  - CMS requested comments on whether certain facilities should be excepted.

CY 2019 Provider-Based Proposals; Clinical Family of Services

- CMS solicited comments regarding:
  - The length of the baseline period
  - The proposed clinical family of services
  - Exceptions for certain types of hospitals
  - Alternative methods to limit expansion and satisfy CMS's goal of slowing or ceasing the acquisition of physician practices and converting them to provider-based HOPDs

Any More Questions?

Or any questions at all?

Your Speakers

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"One business card for your wallet, one for your desk, one for your car, one for your home office, one for your blue suit pocket, one for your brown suit pocket, one for your gray suit pocket..."

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