OBSERVATION SERVICES:

2018 CMS UPDATES...

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Disclosure of Commercial Relationships:

<table>
<thead>
<tr>
<th>Nature of Relationship</th>
<th>Name of Commercial Entity</th>
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<td>Advisory Board</td>
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</tr>
<tr>
<td>Consultant</td>
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<td>Employee</td>
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<td>Board Member</td>
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<td>Speaker’s Bureau</td>
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<td>Patents</td>
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<tr>
<td>Other Relationships</td>
<td>CMS Technical Expert Panel: AMI, HF, pneumonia</td>
</tr>
<tr>
<td></td>
<td>Past CMS APC Advisory Panelist</td>
</tr>
<tr>
<td></td>
<td>Chair – Visits and Observation Subcommittee</td>
</tr>
<tr>
<td></td>
<td>Accreditation Management Board, American College of Cardiology</td>
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Objectives:

A. Understand the structure of the Center for Medicare and Medicaid Services (CMS)

A. Know 4 CMS policies that discourage prolonged observation care
   • definition, C-APC 8011, 2-midnight rule, and the MOON.

B. Understand 3 patient centered observation issues
   • Readmissions, out of pocket costs, and risk of loosing SNF benefit

Background: U.S. Health System

The Nation’s Health Dollar, Calendar Year 2016: Where It Went

Other spending, 20%
Other health, residential, and personal care, 5%
Government administration and net cost of health insurance, 8%
Prescription drugs, 10%
Nursing care facilities and continuing care retirement communities, 5%
Physician and clinical services, 20%
Hospital care, 32%

NOTE: “Other spending” includes Dental services, Other professional services, Home health care, Durable medical equipment, Other nondurable medical products, Government public health activities, and Investment.

National Health Expenditures as a Share of Gross Domestic Product, 1987-2016

The share of GDP devoted to health was 17.9% in 2016


National health spending increased 4.3% in 2016
Annual Growth in Spending by Type of Good and Service, 2015-2016


Annual Growth in Hospital Spending, 2012-2016

2016 highlights:
- Total spending = $1.1 trillion
- Spending increased 4.7%
- Slower growth in 2016:
  - Medicaid
  - Private Health Insurance
  - Residual use and intensity

A. The Anatomy and Physiology of Medicare (or CMS) . . .

- U.S. Government:
  - Judicial Branch
  - Legislative Branch:
    - Senate
    - House of Representatives
  - Executive Branch
    - Cabinets
      - Secretary of State
      - Secretary of Health and Human Services
    - Secretary of Defense
    - etc. . .
Dept of Health and Human Services (DHHS) administers:

1. Assistant Secretary for Health
2. Public Health Service
3. Office of the Surgeon General
4. Public Health Service Commissioned Corps
5. Assistant Secretary for Preparedness and Response
6. Office of the Assistant Secretary for Preparedness and Response
7. Biomedical Advanced Research and Development Authority
8. Assistant Secretary for Legislation
9. Assistant Secretary for Planning and Evaluation
10. Assistant Secretary for Administration
11. Assistant Secretary for Public Affairs
12. Assistant Secretary for Financial Resources
14. Administration for Children and Families
15. Administration on Aging
16. Agency for Healthcare Research and Quality
17. Agency for Toxic Substances and Disease Registry
18. Centers for Disease Control and Prevention
19. Centers for Medicare and Medicaid Services
20. Food and Drug Administration
21. Health Resources and Services Administration
22. Indian Health Service
23. National Institutes of Health
24. Substance Abuse and Mental Health Services Administration

Center for Medicare and Medicaid Services (CMS)

- Employs about 6,000 employees:
  - 4,000 are located at its headquarters in Baltimore
  - The remaining employees are located in:
    - Hubert H. Humphrey Building in Washington, D.C.
    - 10 regional offices
    - Various field offices located throughout the United States.
- The head of the CMS is appointed by the president and confirmed by the Senate.
CMS Regional Offices

- **Region I** – Boston, Massachusetts
  - Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island and Vermont.
- **Region II** – New York City, New York
  - New Jersey, New York, as well as the U.S. Virgin Islands and Puerto Rico.
- **Region III** – Philadelphia, Pennsylvania
  - Delaware, Maryland, Pennsylvania, Virginia, West Virginia and the District of Columbia.
- **Region IV** – Atlanta, Georgia
  - Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee.
- **Region V** – Chicago, Illinois
  - Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin.
- **Region VI** – Dallas, Texas
  - Arkansas, Louisiana, New Mexico, Oklahoma and Texas.
- **Region VII** – Kansas City, Missouri
  - Iowa, Kansas, Missouri, and Nebraska.
- **Region VIII** – Denver, Colorado
  - Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.
- **Region IX** – San Francisco, California
  - Arizona, California, Hawaii, Nevada, the Territories of American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.
- **Region X** – Seattle, Washington

Medicare administers:

1. **Medicare**
2. Medicaid
3. State Children’s Health Insurance Program (SCHIP)
4. Clinical Laboratory Improvement Amendments (CLIA)
5. Health Insurance Portability and Accountability Act (HIPAA) of 1996

Note: Medicare eligibility is determined by the Social Security Administration.
Medicare Parts

- **Part A**: Hospital Insurance - 1966
- **Part B**: Medical Insurance
- **Part C**: Medicare Advantage plans ("Medicare HMO")
- **Part D**: Prescription drug plans

### Part A: Hospital Insurance

- Part A covers *inpatient* hospital stays, including semiprivate room, food, and tests.
  - Definition of an inpatient – to be discussed

- Part A — For each benefit period, a beneficiary will pay:
  
  How much???
Part A: Hospital Insurance

• Part A covers inpatient hospital stays, including semiprivate room, food, and tests.
  - Definition of an inpatient – to be discussed

• Part A — For each benefit period, a beneficiary will pay:
  - A Part A deductible of $1,340 (in 2018) for a hospital stay of 1–60 days.
    • A $335 per day co-pay (in 2018) for days 61–90 of a hospital stay.
    • A $670 per "lifetime reserve day" day co-pay (in 2018) after day 90 of each benefit period (up to a maximum of 60 days over one’s lifetime).
  - Benefit period – 60 days following the conclusion of inpatient or SNF care.
    • Reset if inpatient readmission occurs.

• Skilled Nursing Facility Stay - in 2018:
  ■ $0 for the first 20 days of each benefit period
  ■ $167.50 per day for days 21–100 of each benefit period
  ■ All costs after day 100 of the benefit period

• Covers hospice benefits

Ref:
• https://www.medicare.gov/Pubs/pdf/11579-Medicare-Costs.pdf

Part A: Rehab or Skilled Nursing Facility (SNF) payment

• The Four “IF”s:
  1. A preceding hospital stay must be at least three days as an inpatient, three midnights, not counting the discharge date.
  2. The nursing home stay must be for something diagnosed during the hospital stay or for the main cause of hospital stay.
  3. If the patient is not receiving rehabilitation but has some other ailment that requires skilled nursing supervision then the nursing home stay would be covered.
  4. The care being rendered by the nursing home must be skilled.
    - Medicare part A does not pay stays which only provide custodial, non-skilled, or long-term care activities, including activities of daily living (ADL) such as personal hygiene, cooking, cleaning, etc.
Hospital Inpatient Readmission Penalties . . .

- Medicare will take back hospital inpatient payments and far more, **4 to 18 times** the initial payment, if an above-average number of patients from the hospital are readmitted within 30 days.
- These readmission penalties apply after some of the most common treatments: pneumonia, heart failure, heart attack, COPD, knee replacement, hip replacement

Quality Improvement Organizations – “QIO”s

- a group of health quality experts, clinicians, and consumers organized to improve the care delivered to people with Medicare.
- Objectives – to improve effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries:
  - Improve quality of care for beneficiaries
  - Protect the integrity of the Trust Fund by ensuring that CMS pays for what is **“reasonable and necessary”** and in the most **“appropriate setting”**
  - Address – complaints, appeals, violations of EMTALA, etc.
**INPATIENT DEFINITION**

**Effective 2016**

- A 2-midnight **benchmark**: FOR DOCTORS
  - An inpatient is a patient that is expected to stay in the hospital at least two midnights:
    - 24 hours and 1 minute, or 47 hours and 59 minutes
    - “Clock” starts at triage
  - Outpatient time (ED or observation) counts
  - Inpatient stays < 2-MN not paid as an inpatient
    - except death, transfer, AMA, etc

- A 2-midnight **presumption**: FOR REVIEWERS
  - If a patient met benchmark criteria, the admission will not be scrutinized by reviewers (RAC, MAC, etc)

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**CMS 2019 Update:**

**IPPS-inpatient Admission Orders Documentation requirements**

- Effective 10/1/2018
  - “no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare part A payment.”
  - revise the regulation at 42 CFR 412.3(a) to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.

- ......but......
  - this policy would not change the requirement that a beneficiary becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission.
Medicare Part B:

1. *Outpatient hospital procedures and visits*
2. Physician and nursing services
3. X-rays
4. Laboratory and diagnostic tests
5. Influenza and pneumonia vaccinations
6. Blood transfusions
7. Renal dialysis
8. Limited ambulance transportation
9. Immunosuppressive drugs for organ transplant recipients
10. Chemotherapy
11. Hormonal treatments such as lupron
12. Other outpatient medical treatments administered in a doctor's office.
13. Medication administered by the physician during an office visit
14. Durable Medical Equipment

Medicare Part B - **coverage**

- 2018 “covered” services –
  - Begins after a 2018 yearly deductible of **$183**
  - *Then* Medicare pays 80% of approved services
    - Patients pays a **20% co-insurance**

- Exceptions:
  - Most lab services – 100%
  - Outpatient mental health services – 55% (planned trending toward 20% over several years)

- **Medigap** (or Medicare Supplemental Insurance)
  - Covers Medicare deductibles and non-covered costs
  - ~25% of Medicare beneficiary have some form of Medigap

**DEFINITION: OBSERVATION - 2018**

Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)

Date of revision: (Rev. 1766, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

290.1 - Observation Services Overview

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment, that are **furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients** or if they are able to be discharged from the hospital . . .

... Observation services are covered **only when provided by order of a physician** or another individual authorized by State licensure law and hospital bylaws to admit patients to the hospital or to order outpatient tests.

. . . In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. . . In the majority of cases, the decision . . . can be made in **less than 48 hours, usually in less than 24 hours**.

---

Current CMS Payment Policy for Observation Services - **APC 8011** (effective 2016):

“**Comprehensive Observation Services**” APC

- **Current Hospital Payment Requirements:**
  1. **Physician order** and documentation supporting the need for observation
  2. **Preceding (packaged) HOSPITAL visit:** any of the following
     - Clinic visit (HCPCS code G0463)
     - Type A or B ED visit - level 1 to 5 (HCPCS code 99281-99285, HCPCS G0380-4)
     - Critical care (CPT code 99291)
     - Direct referral for observation (HCPCS code G0379, APC 5013)
  3. **Minimum of 8 hours of observation:**
     - "observation services of substantial duration"
     - HCPCS code G0378 X 8 or more
  4. **No associated “T-status” procedure** on the same or preceding day
     - Surgery or procedures

- **NEW Status Indicator “J2” for C-APC**
- **2018 APC 8011 Payment Amount = $2,289**
  - Includes all other services (stress test, MRI, etc)
  - It does **NOT** include two things:
    1. **SNF inpatient time**
    2. **Self administered meds**
T-Status Procedures: Examples

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Desc</th>
<th>SI</th>
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<tbody>
<tr>
<td>43239</td>
<td>Egd biopsy single/multiple</td>
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</tr>
<tr>
<td>62270</td>
<td>Spinal fluid tap diagnostic</td>
<td>T</td>
</tr>
<tr>
<td>43235</td>
<td>Egd diagnostic brush wash</td>
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</tr>
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<tr>
<td>45380</td>
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</tr>
<tr>
<td>43247</td>
<td>Egd remove foreign body</td>
<td>T</td>
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<tr>
<td>45378</td>
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Medicare Outpatient (OPPS) Rulemaking process:

- **July**: Proposed Rule (Federal Register)
  - **2019** – Observation – **NO CHANGE!!!**
- **July – Sept**: Open comment period
  - Public / stakeholder organizations
  - HOP (Hospital Outpatient Panel)
  - Med Pac
- **Sept – Nov**: Closed comment period
- **Nov**: Final Rule (Federal Register)
  - Program Memorandum
  - Hospital Manual
  - CMS website
- **Jan 1**: Implementation date
VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

• As we did in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59373), for CY 2019, we are proposing to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies.

C. Four CMS Policies That Discourage Prolonged Observation Care

1. The definition of Observation Services
   • Less than 24hr, rarely over 48hr

2. Comprehensive C-APC 8011
   • Packages all services into a single payment

3. The 2-midnight rule

4. The “NOTICE Act” and the “MOON”
1. DEFINITION: OBSERVATION

Observation services must also be reasonable and necessary to be covered by Medicare. In **only rare and exceptional cases** do reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient **can be made in less than 48 hours, usually in less than 24 hours**.

2. Comprehensive APC 8011:
CMS Favors Observation Services - 7 year Observation Facility Payment Trend

<table>
<thead>
<tr>
<th>Year</th>
<th>CMS Payment</th>
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<tr>
<td>2010</td>
<td>$705.27</td>
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<tr>
<td>2011</td>
<td>$714.33</td>
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<td>2012</td>
<td>$720.64</td>
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<td>2013</td>
<td>$798.47</td>
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<td>2014</td>
<td>$1,199.00</td>
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<td>2015</td>
<td>$1,234.22</td>
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<td>2016</td>
<td>$2,174.22</td>
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<td>2017</td>
<td>$2,221.70</td>
</tr>
<tr>
<td>2018</td>
<td>$2,289.33</td>
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3. The Two-Midnight Rule

Vulnerabilities Remain Under Medicare’s 2-Midnight Hospital Policy

- Hospitals are billing for many short inpatient stays that are potentially inappropriate under the policy; Medicare paid almost $2.9 billion for these stays in FY 2014.
- Medicare pays more for some short inpatient stays than for short outpatient stays, although the stays are for similar reasons.
- Hospitals continue to bill for a large number of long outpatient stays.
- An increased number of beneficiaries in outpatient stays pay more and have limited access to SNF services than they would as inpatients.
- Hospitals continue to vary in how they use inpatient and outpatient stays.

CMS needs to address these continuing vulnerabilities by improving oversight of hospital billing under the 2-midnight policy and increasing protections for beneficiaries.

Figure 2: Changes in Types of Hospital Stays, FY 2013 to FY 2014

<table>
<thead>
<tr>
<th>Setting</th>
<th>Length of Stay</th>
<th>FY 2014</th>
<th>Change From FY 2013</th>
<th>Percentage Change From FY 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient</td>
<td>Short</td>
<td>2,709,897</td>
<td>281,156</td>
<td>11.6%</td>
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<tr>
<td></td>
<td>Long</td>
<td>748,337</td>
<td>-21,248</td>
<td>-2.8%</td>
</tr>
<tr>
<td>Inpatient</td>
<td>Short</td>
<td>1,074,257</td>
<td>-116,050</td>
<td>-9.9%</td>
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<tr>
<td></td>
<td>Long</td>
<td>8,009,537</td>
<td>-444,734</td>
<td>-5.5%</td>
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<tr>
<td>Total</td>
<td></td>
<td>12,542,038</td>
<td>-2,886</td>
<td>-2.3%</td>
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4. The “NOTICE Act” and the “Medicare Outpatient Observation Notice” (or “MOON”)

- Not a policy, a LAW - Effective August 6, 2016
- If a patient will be receiving observation services for more than 24 hours, then within 36 hours the hospitals must notify patients (written and oral) in plain language:
  - That they are “outpatient” status and is not an “inpatient” of the hospital
  - The reasons why the patient is outpatient status
  - The implications of remaining in outpatient status – specifically, the related financial consequences including:
    1. Deductibles
    2. Coinsurance
    3. The lack of coverage for certain items or services not covered by Medicare
    4. The time spent as an outpatient will not count towards the 3-day acute care qualifying stay requirement for coverage of a skilled nursing facility.

- The notification must be signed by both the patient (or designee) and hospital staff.
  - If patients refuse to sign, the refusal must be documented.

The current “MOON”

![Image of Medicare Outpatient Observation Notice](image-url)
D. Patient Centered Issues with Observation Services

1. Readmissions

2. Out-of-Pocket Costs

3. Self Administered Medications

4. Risk of Loosing SNF Benefit

1. Readmissions: Is observation “hiding” re-admissions? ...

Hospital Inpatient Readmission Penalties:

• Medicare will take back hospital inpatient payments and far more, **4 to 18 times** the initial payment, if an above-average number of patients from the hospital are readmitted within 30 days.

• These readmission penalties apply after some of the most common treatments: pneumonia, heart failure, heart attack, COPD, knee replacement, hip replacement
Analyzed data from 3,387 hospitals, between 2007 and 2015
- Targeted conditions = AMI, HF, pneumonia
- Readmissions declined:
  - Non-targeted conditions: 15.3% to 13.1% (-2.2%)
  - Targeted conditions: 21.5% to 17.8% (-3.7%)
- Observation visits increased:
  - Non-targeted conditions: 2.5% to 4.2% (+1.7%)
  - Targeted conditions: 2.6% to 4.7% (+2.1%)
- No association between re-admissions and observation stays
  - Observation visits did not account for hidden readmissions.

Outcomes after observation stays among older adult Medicare beneficiaries in the USA: retrospective cohort study

Kumar Dharamarajan,1 Li Qin,2 Maggie Bienlein,3 Jennie ES Choi,4 Zhenqiu Lin,2 Nihar R Desai,1 Erica S Spatz,1 Harlan M Krumholz,1 Arjun K Venkatesh6

<table>
<thead>
<tr>
<th>Initial ED disposition</th>
<th>Return: ED</th>
<th>Return: Obs</th>
<th>Return: IP</th>
<th>Return: All</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED=&gt;home</td>
<td>9.8%</td>
<td>1.4%</td>
<td>10.6%</td>
<td>19.9%</td>
</tr>
<tr>
<td>ED=&gt;Obs</td>
<td>8.4%</td>
<td>2.9%</td>
<td>11.2%</td>
<td>20.1%</td>
</tr>
<tr>
<td>ED=&gt;IP</td>
<td>7.3%</td>
<td>1.2%</td>
<td>15.3%</td>
<td>21.8%</td>
</tr>
</tbody>
</table>

Data represents type 1 through type 4 settings
All Medicare patients 2006-2011
Recidivism similar to ED patients
1/5 Medicare ED patients will return in 30 days
2. Out of Pocket costs are increasing

Cumulative increases in health costs, amounts paid by insurance, amounts paid for cost sharing and workers wages, 2005-2015


Do observation stays cost more?

Medicare – NO!  Patients – NO

[exception – PROCEDURES]
Medicare out of pocket costs: simple math …

• Observation:
  • APC = **$459**
    • $2,289 × 0.2
  • Self Adm Meds ~ $207
  • If both = **$664**
    • $459 + $207

• Inpatient:
  • **$1,340** deductible

20% sample of Medicare data from 2010-2012:

• Medicare claims 37,353,380
  • 20% sample 7,470,676
  • Observation visit (OV) 691,760 (9.3% of 20% sample)
  • ≥2 Observation visits 41,385 (6.0% of Obs visits)
  • Obs cost > IP deductible 11,008 (1.6% of Obs visits)

IP deductible = $1,100
Ave Obs = $469
Obs >2 visits = $947
• The majority of Medicare beneficiaries use supplemental insurance to reduce their out-of-pocket burden:
  • Employer based plans
  • Medicaid
  • Federally regulated Medigap plans
• 1/3 of Medicare beneficiaries use Medicare Advantage plans that negotiate different reimbursement structures for observation stays.
• Proposal – use more specific language when referring to cost

3. Self Administered Medications (SAMs)

• OIG data:
  • Average out of pocket cost to patients:
    • $207
    • Unchanged between 2013 and 2014
  • Medications that a patient would give themselves
  • Not part of acute condition
  • Not given by IV infusion
  • May or may not include subQ injections
4. Risk of losing “SNF”: OIG

- 2012 OIG analysis of CMS data:
  - 3 days, but less than 3 IP days = 617,702
  - Received SNF services = 25,245 (4%)
  - This represent 0.6% of Medicare Observation patients

- 2013 vs 2014 OIG analysis of CMS data:
  - 3 days, but less than 3 IP days = 633,148 (6% increase over 2013)
    - “Never an inpatient” = 32% of total
      - This group decreased 15.3% over 2013
    - “Started as obs” then an inpatient = 68% of total
      - This group increased 20% over 2013
    - FAILURE TO MAKE A TIMELY DISPOSITION!!! – the case for a Type 1 Unit

<table>
<thead>
<tr>
<th>Type of Stay</th>
<th>FY 2014</th>
<th>Change From FY 2013</th>
<th>Percentage Change From FY 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 or more nights as outpatient and never admitted as inpatient</td>
<td>200,468</td>
<td>-36,910</td>
<td>-15.3%</td>
</tr>
<tr>
<td>Begun as outpatient and admitted as inpatient</td>
<td>432,740</td>
<td>72,342</td>
<td>20.1%</td>
</tr>
<tr>
<td>Total</td>
<td>633,148</td>
<td>36,910</td>
<td>6.1%</td>
</tr>
</tbody>
</table>


- 100% of 2009 Medicare inpatient and outpatient claims:
  - >1 million observation visits
    - 2.9% (29,324) discharged to a SNF
      - 62% came from the SNF
      - 8% came from a NH
      - 26% (7,537) came from community (at risk)
    - 0.75% (7,537) with SNF benefit at risk
      - NOTE: OIG (above) reported that CMS still paid 92% of these (inappropriately).
CMS should remove the 3-day rule

Medicare enrollees compared:

- 3-day rule actually increases hospital LOS by 0.7 days
- Removal of the rule is not associated with an increase in SNF placement or length of stays

Summary

- The people making major decisions (or mistakes) are well intended people like you and I . . . Who don’t know what they don’t know.
  - They NEED **YOU** to educate them

- Medicare likes “good” observation services and does not like prolonged observation services

- Type 1 observation units are the essential link to good observation care
References:

- CMS: https://www.cms.gov
- CMS: https://en.wikipedia.org/wiki/Medicare_(United_States)
- MAC: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MedicareAdministrativeContractors.html
- Federal Register: https://www.federalregister.gov
- Federal Register: https://www.federalregister.gov
- Proposed HF readmission methods: https://www.qualitynet.org/dcs/ContentServer?cid=1228775330395&pagename=QnetPublic%2FPPage%2FQnetTie dlePage
Where to find Medicare Part B coverage criteria:

- **National Coverage Determinations (NCD)**
  - at the national level

- **Local Coverage Determinations (LCD)**
  - multi-state area managed by a specific regional Medicare Part B contractor

- **Other sources:**
  - The Code of Federal Regulations (CFR)
  - The Social Security Act
  - [The Federal Register](https://www.federalregister.gov/)