Medicare Appeals for Health Care Providers: Understanding the Appeals Process and the Impact of the Backlog
Maximizing Reimbursement Performance and Mitigating Risk

THURSDAY, FEBRUARY 5, 2015
1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today’s faculty features:

Stephanie Greene, Chief Consulting Officer, ACU-Serve, Cuyahoga Falls, Ohio
Amy Lerman, Senior Associate, Epstein Becker & Green, Washington, D.C.

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Medicare Appeals for Health Care Providers: Understanding the Appeals Process and the Impact of the Backlog

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Agenda

A. Understanding the Medicare Appeals Process and the Appeals Backlog
   1. The Medicare Program and the Appeals Process
   2. OMHA and the Medicare Appeals Backlog
   3. OMHA’s Appellant Forums
   4. OMHA’s Process Improvements and Other Potential Remedies

B. A Report “From the Trenches”
   1. Get to Know the MACs
   2. Issues That MACs Are Most Focused On
   3. A “Real” Perspective on the Medicare Appeals Backlog

C. Focus on Compliance – A Solution, or Merely a Stopgap to Appeals?
   1. Overview of Compliance
   2. Compliance Efforts to Improve Reimbursement Performance and Mitigate Risk
   3. Risks of Non-Compliant Behavior
Understanding the Medicare Appeals Process
The Medicare Program: A Quick Overview

- **Parts A & B – “Original Medicare”**
  - Part A provides Hospital Insurance – helps pay for inpatient care in hospitals or skilled nursing facilities (following hospital stays), some home health services, and hospice services.
  - Part B provides Supplementary Medical Insurance – helps pay for physicians’ services and other medical services and supplies that are not covered by Part A.

- **Part C – Medicare Advantage Program**
  - Medicare Advantage plans are available in many areas of the country.
  - Beneficiaries with Medicare Parts A and B can choose to receive all of their health care services under Part C through a Medicare Advantage plan.

- **Part D – Medicare Prescription Drug Program**
  - Part D helps pay for certain medications doctors prescribe for treatment.
  - Beneficiaries with Medicare Parts A and B can choose to obtain prescription drugs through a Part D plan.
The Medicare Program – Focus on Part B

- Covers two types of services:
  - Medically Necessary Services
  - Preventive Services (e.g., mammography, colorectal cancer screening)

- Coverage and reimbursement based on various factors:
  - Federal Laws and Regulations (e.g., SSA, CFR)
  - State Laws and Regulations
  - National Coverage Decisions (NCDs)
  - Local Coverage Decisions (LCDs)
  - CMS Manuals and Other Subregulatory Guidance
The Medicare Appeals Process: An Overview

“In general, the procedures described in paragraph (a) of this section [beneficiary claims appeals] are also available to parties other than beneficiaries either directly or through a representative acting on a party’s behalf, consistent with the requirements of this subpart I [Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)].” (42 C.F.R. § 405.904(b))
The Medicare Appeals Process: Step by Step

Office of Medicare Hearings & Appeals (OMHA)

- Responsible for hearings before Administrative Law Judges (ALJs) on a range of Medicare appeals – *third level of Medicare appeals process*

- Appeals must be filed within 60 days of receiving a reconsideration decision

- *Interest still accrues*

- ALJ hearings are conducted *de novo* (independent evaluation)

- Hearings conducted either “on the record” or live

- Difficult to submit additional evidence – may have to show “good cause”

- ALJs are supposed to decide appeals within 90 days after all briefs and other materials filed – but can take longer

- *Recoupment is not halted when an ALJ appeal is filed*
OMHA Timeline of Recent Events Regarding Medicare Appeals Backlog

- **December 2013**
  - Letter to Medicare providers from OMHA’s Chief ALJ, Nancy Griswold, announcing that due to OMHA’s caseload it was “temporarily suspend[ing] the assignment of most new requests for an [ALJ] hearing to allow OMHA to adjudicate appeals involving almost 357,000 claims . . . already assigned to its 65 [ALJs].”

- **February 2014**
  - OMHA hosted first Appellant Forum

- **October 2014**
  - OMHA hosted second Appellant Forum

- **December 2014**
  - $1.1 trillion appropriations bill signed into law by President Obama (“CRomnibus”), which will fund the federal government through FY 2015; includes $87 million in funding for the OMHA
OMHA Caseload

- Projected delay in docketing new requests = **20-24 weeks**
- Average processing time for appeals decided in FY 2015 = **547.1 days**.

**Quarterly Receipts**

- Represents cases with Request for Hearing Date in listed year
- Excludes reopened and combined appeals
- FY14 receipts may be incomplete due to data entry backlog. Receipts complete as of January 2014

**Source:** Office of Medicare Hearings and Appeals, [http://www.hhs.gov/omha/Data/Current%20Workload/index.html](http://www.hhs.gov/omha/Data/Current%20Workload/index.html)
OMHA’s Deferred Assignment Process

- Introduced by OMHA in December 2013
- Applicable to ALJ hearing requests submitted after April 1, 2013
- New requests for ALJ hearings are entered into OMHA’s case processing system and held until they can be accommodated on an ALJ’s docket
- When a request is assigned to an ALJ, OMHA sends a Notice of Assignment
  - Based on current workload and volume of new requests, assignments of requests for ALJ hearings may be delayed for up to 28 months
  - Despite these delays, OMHA continues to process Part D prescription drug denial cases that qualify for expedited status within 10 days and screens all incoming requests to ensure beneficiary issues are prioritized
OMHA Appellant Forums

- Held in February 2014 and October 2014
- Discussed three reasons for dramatic increase in appeals volume:
  - Increasing numbers of Medicare beneficiaries
  - Increase in dual eligibles workload as state Medicaid agencies become more active
  - *Expansion of post-payment audits, e.g., RACs and ZPICs*
- Focused on developing and implementing “holistic” solutions
- Listened to attendee feedback, including:
  - Delays at first two levels of appeals process, i.e., before OMHA is even involved
  - “Technical” versus “medical necessity” denials
  - Refusals by MACs / QICs to reopen decisions when reconsideration appropriate
  - Delays in appeals a significant threat to providers’ continued existence
OMHA Appellant Forums

- Attendees advised to be mindful of certain considerations when filing requests for ALJ hearings:
  - Not attaching medical records or other documentary evidence to requests for ALJ hearings
  - Including the Medicare Appeal Number for the reconsideration being appealed on the Request for ALJ Hearing form, or including a copy of the first page of the QIC’s reconsideration decision
  - Refraining from sending “courtesy copies” of requests for ALJ hearings to the QIC that issued the reconsideration, or to the MAC that issued the redetermination
  - Not submitting medical records or other documentary evidence already submitted as part of the original claims submission or an earlier level of the appeals process
  - If submitting new evidence to ALJ not previously submitted at a prior level of the appeals process, evidence must be accompanied by a statement explaining why it was not previously submitted (42 C.F.R. § 405.1018), and ALJ will determine whether there is good cause to submit the evidence for the first time at the ALJ level (42 C.F.R. § 405.1028)
Any Relief in Sight? OMHA’s Process Improvements and Other Potential Remedies

- OMHA Process Improvements
- OMHA Request for Information
- American Hospital Association Litigation
- CMS’s “68 Percent Solution”
- The Medicare DMEPOS Audit Improvement and Reform (AIR) Act of 2014
OMHA Process Improvements

- Opening of new OMHA field office in Kansas City, MO (Feb. 2014)
- Development of a new OMHA adjudication manual
- Consideration of statistical sampling methods (would be done only with appellant consent)
- Implementation of alternative dispute resolution methods
- Launch of two pilot projects (July 2014):
  - Statistical Sampling Pilot
  - Settlement Conference Facilitation Pilot
- Modernization of OMHA’s IT infrastructure, including:
  - ALJ Appeal Status Information System (AASIS) – launched end of 2014
  - Electronic Case Adjudication and Processing Environment (ECAPE) – coming soon
OMHA Request for Information (OMHA-1401-NC)

- Published in Federal Register in Nov. 2014; comments were due in Dec. 2014
- Solicited “suggestions for addressing the substantial growth in the number of requests for hearing filed with [OMHA], and backlog of pending cases.”
  - Suggestions related to the current initiatives for addressing the increased workload and/or backlog of appeals at the ALJ level that comply with current statutory authorities and requirements?
  - Other suggestions for addressing the increased workload and/or backlog of appeals at the ALJ level that comply with current statutory authorities and requirements?
  - Any current regulations that apply to the ALJ level of the appeals process that could be revised to streamline the adjudication process while ensuring that parties to appeals are afforded opportunities to participate in the process and are kept apprised of appeals related to claims submitted by them or on their behalf?

- Filed mandamus complaint in May 2014
- Sought to compel the U.S. Department of Health and Human Services to meet statutory deadlines for timely review of Medicare claims denials (Medicare law requires an ALJ to hold a hearing and render a decision within 90 days (42 U.S.C. § 1395ff(d)(1)(a)))
- Court dismissed case in December 2014
  - Acknowledged that OMHA is “saddled with a workload it cannot possibly manage.”
  - Ruled that “[w]hile the Court sympathizes with Plaintiffs’ plight, for the time being the waiting game must go on. HHS’s delay in processing their administrative appeals, while far from ideal, is not so egregious to warrant intervention.”
  - Noted that “Congress is well aware of the problem, and Congress and the Secretary are the proper agents to solve it. In such situations—where an agency is underfunded and where it is processing Plaintiffs’ appeals on a first-come, first-served basis—the Court will not intervene.”
- AHA plans to appeal the decision
CMS’s “68 Percent Solution”

- Introduced by CMS in September 2014
- Only made available to acute care and critical access hospital providers, aimed at reducing volume of short-stay inpatient claims pending appeals
- Applicable to FFS denials for admissions prior to October 1, 2013
- What’s the Solution? An administrative agreement to resolve pending appeals or waive the right to request an appeal in exchange for a “timely partial payment” of 68 percent of the net payable amount
- What’s the Catch? There are several:
  - Not available to all Medicare providers
  - May not mesh well with some providers “appeal philosophies”
  - Potential payment differential between 68% of net value and Part B rebilling value
  - “935 Interest”
- Providers submitted required documents accepting the 68 percent solution by October 31, 2014, unless granted an extension by CMS
The Medicare DMEPOS Audit Improvement and Reform (AIR) Act of 2014 (H.R. 5083)

- Introduced in July 2014 by Congresswoman Renee Ellmers (R-NC) with strong bipartisan support

**Would only be applicable to DMEPOS suppliers**

- Suppliers would receive a score on their error rates; suppliers with low error rates would, in turn, receive fewer audits
- Suppliers with error rates of 15 percent or lower would only be subject to one random audit for the year they have a low error rate
- Clinical inference would be restored in the audit process
- Look-back periods would be limited to 3 years rather than 5 years for MACs, and 4 years for RACs
- MACs and RACs would be required to provide quarterly training on avoiding frequent payment errors, including notice of all new audit procedures and education, to avoid denials based on “clerical” types of errors

- Expected to be re-filed in the new Congress
A Report
“From the Trenches”
Medicare System

- Social Security Act
- Code of Federal Regulations (CFR)
- Program Manuals
- National Coverage Decisions (NCDs)
- Local Coverage Decisions (LCDs)
**Social Security Act**

(E) Clinical conditions for coverage.—

(i) In general.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) Requirements.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.
Medicare Program Manuals

- Medicare Program Integrity Manual
  - Section 1893(b)(1) establishes the Medicare Integrity Program which allows contractors to review activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title . . . , including medical and utilization review and fraud review. . . .

- National Coverage Decisions (NCDs)
  - The statutory and policy framework within which National Coverage Decisions are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The National Coverage Decisions Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. National Coverage Decisions have been made on the items addressed in this manual.
DME DMACs
DME DMACs

- **Jurisdiction A** -- National Heritage Insurance Company
  - Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont

- **Jurisdiction B** -- National Government Services
  - Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin
  - [http://www.ngsmedicare.com](http://www.ngsmedicare.com)
DME DMACs

- **Jurisdiction C** -- CIGNA Government Services Administrators
  - Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia
  - [http://www.cgsmedicare.com](http://www.cgsmedicare.com)

- **Jurisdiction D** -- Noridian Administrative Services
  - Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and Wyoming
  - [https://www.noridianmedicare.com](https://www.noridianmedicare.com)
DMAC Guidance

- Local Coverage Decisions (LCDs)
  - Articles
- Education and Training
  - Ask the Contract (ATC) Calls
  - FAQs
  - Webinars and Seminars
  - Audit Denial Results and Reasons
- Supportive Documents
  - Documentation Checklists
  - Physician Letters
Audit Activity

- Generally, audits differentiate based upon **how** the claim is selected, and **when** the claim is audited
  - *Provider-specific* claims vs. **random** claims
    - DMAC audits are commonly random audits
    - ZPIC audits are provider-specific audits
  - *Pre-payment* claims vs. **post-payment** claims
    - Pre-payment slows cash cycle
    - Post-payment opens provider up to overpayment demands
Audit Consequences

- **Primary Consequence: Denial of the Claim Audited**
  - Denials of future claims
  - Overpayment demands for past claims
- Referral to more aggressive provider-specific audits
  - ZPIC most common
- Corrective Action Plans with continued audits
- Extrapolation of prior payments
  - Error rate applied across universe sampled
- Referral to enforcement agencies (DOJ and OIG)
  - Institution of civil monetary penalties or criminal sanctions
- Payment suspension
- Exclusion from Federal health care programs
Widespread Pre-Payment Reviews by DMACs

- Each jurisdiction performs its own pre-payment medical reviews
- Most common audit targets:
  - Glucose monitors and supplies
  - Knee / LSO orthoses
  - Nebulizer medications
  - Negative wound therapy
  - Oxygen and oxygen equipment
  - Power mobility devices
  - Positive airway pressure devices
- Upcoming medical reviews:
  - Ventilators
  - Osteogenesis simulators
DME Audit Activity – DMAC Audit Outcomes

- **Widespread Pre-Payment Review Results**
  - WOPD
    - 75% denial
  - Glucose Monitors and Supplies
    - 92-98.6% denial
  - Orthoses
    - 81-100% denial
  - Nebulizers (compressors) and Medications
    - 71-93% denial
  - Negative Wound Therapy
    - 65% denial
  - Hospital Beds
    - 60-86% denial
DME Audit Activity – DMAC Audit Outcomes

- **Widespread Pre-Payment Review Results**
  - Oxygen and Oxygen Equipment
    - 55-77% denial
  - Mobility Devices
    - 44-80% denial for power
    - 80-91% denial for manual
  - Wheelchair Cushions
    - 55-75% denial
  - Positive Airway Pressure Devices
    - 53-83.5% denial for CPAP / BiPAP
    - 75% denial for RAD
  - Urinary Catheters
    - 73% denial
DME Audit Activity – DMAC Audit Outcomes

- **Widespread Pre-Payment Review Results**
  - Diabetic Shoes
    - 76-78% denial
  - Enteral Nutrition
    - 59-78% denial
  - External Breast Prostheses
    - 61% denial
  - Pressure Reducing Support Surfaces
    - 64-77% denial
  - Immunosuppressive Drugs
    - 65-70% denial
  - Lower Limb Prostheses
    - 44-87% denial
DME Audit Activity – DMAC Audit Outcomes

- **Widespread Pre-Payment Review Results**
  - TENS
    - 95-98% denial
  - Vacuum Erection Systems
    - 69% denial
### Summary -- Medicare Types of Reviews

<table>
<thead>
<tr>
<th>Type</th>
<th>Types of Claims</th>
<th>How selected</th>
<th>Volume of Claims</th>
<th>Type of Review</th>
<th>Purpose of Review</th>
<th>Other Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QIO</strong></td>
<td>Inpatient Hospital claims only</td>
<td>All claims where hospital submits an adjusted claim for a higher-weighted DRG</td>
<td>Very small</td>
<td>1. Prepay &amp; Concurrent (Patient still in hospital) 2. Complex Only</td>
<td>To prevent improper payments through DRG upcoding To resolve discharge disputes between beneficiary and hospital</td>
<td>Quality Reviews</td>
</tr>
<tr>
<td><strong>CERT</strong></td>
<td>All Medical Claims</td>
<td>Randomly</td>
<td>Small</td>
<td>1. Postpay only 2. Complex only</td>
<td>To measure improper payments</td>
<td>None</td>
</tr>
<tr>
<td><strong>SMRC</strong></td>
<td>All Medical Claims</td>
<td>Randomly</td>
<td>Small</td>
<td>1. Postpay only 2. Complex</td>
<td>To identify underpayments and overpayments</td>
<td>None</td>
</tr>
<tr>
<td><em><em>Medical Review Units</em> at MACs</em>*</td>
<td>All Medicare FFS Claims</td>
<td>Targeted</td>
<td>Depends on number of claims with possible improper payments for this provider</td>
<td>1. Prepay &amp; Postpay Automated, &amp; Complex</td>
<td>To prevent future improper payments</td>
<td>1. Education 2. Appeals</td>
</tr>
<tr>
<td><strong>Medicare Recovery Auditors</strong>*</td>
<td>All Medicare FFS Claims</td>
<td>Targeted</td>
<td>Depends on number of claims with possible improper payments for this provider</td>
<td>1. Postpay 2. Automated and Complex</td>
<td>To detect and correct past improper payments</td>
<td>None</td>
</tr>
<tr>
<td><strong>PSC / ZPICS</strong></td>
<td>All Medicare FFS Claims</td>
<td>Targeted</td>
<td>Depends on number of potentially fraudulent claims submitted by provider</td>
<td>1. Prepay and Postpay 2. Automated and Complex</td>
<td>To identify potential fraud</td>
<td>Refer to other agencies as appropriate</td>
</tr>
<tr>
<td><strong>OIG</strong></td>
<td>All Claims</td>
<td>Targeted</td>
<td>Depends on number of potentially fraudulent claims submitted by provider</td>
<td>1. Postpay 2. Complex</td>
<td>To identify fraud</td>
<td>Refer to other agencies as appropriate</td>
</tr>
</tbody>
</table>
If you have to fight to ALJ, and handle each claim separately, you will submit 33 appeals and take 28 months to get all claims to ALJ.
If you have to fight to ALJ, and group appeals, you will submit 10 appeals and take 28 months to get all claims to ALJ
### Hot Spot -- Audit Impact on Rentals

<table>
<thead>
<tr>
<th>Rental:</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>7</th>
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<th>10</th>
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<tbody>
<tr>
<td>Hold Claims</td>
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<td>AD</td>
<td>DN</td>
<td>RD</td>
<td>●</td>
<td>RC</td>
<td>●</td>
<td>AU</td>
<td>●</td>
<td>RD</td>
<td>●</td>
<td>RC</td>
<td>AU</td>
</tr>
</tbody>
</table>

- ● - Claim
- AD - Audit
- DN - Denied
- RD - Redetermination
- RC - Reconsideration
- ALJ - Administrative Law Judge

If you have to fight to ALJ, and **hold claims**, you will submit **6 appeals** and take **28 months** to get all claims to ALJ.
Appeals – Do They Work?

- FY 2013 Statistics
  - MACs processed over 934 million Part B claims, of which 101 million were denied
  - DME MACs processed over 71 million claims of which 11 million were denied
  - *Only approximately 2.9% of the denials were appealed* (3.2 million Part B redeterminations)
Redetermination Appeal Results

Redetermination Categories – Part B

<table>
<thead>
<tr>
<th>Appeal Category</th>
<th>Decided Claims</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>1,391,007</td>
<td>42.9%</td>
</tr>
<tr>
<td>Durable Medical Equipment (DME)</td>
<td>1,358,662</td>
<td>41.9%</td>
</tr>
<tr>
<td>Ambulance</td>
<td>182,335</td>
<td>5.6%</td>
</tr>
<tr>
<td>Other (Preventative Services, Vision, etc.)</td>
<td>178,000</td>
<td>5.5%</td>
</tr>
<tr>
<td>Lab</td>
<td>132,307</td>
<td>4.1%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>3,242,311</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

DME Redeterminations

The numbers ....
- 1,358,662 DME claims appealed to Redetermination
- 373,632 claims fully favorable (27.5%)
Redetermination Appeal Results

![Graph showing 2013 Redetermination Timeliness]

Note: Generally, redeterminations must be issued within 60 days of the request for appeal.
Reconsideration Appeal Results

<table>
<thead>
<tr>
<th>Appeal Category</th>
<th>Decided Claims</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen</td>
<td>114,734</td>
<td>26.0%</td>
</tr>
<tr>
<td>Surgical Dressings</td>
<td>78,167</td>
<td>17.7%</td>
</tr>
<tr>
<td>Glucose Monitors</td>
<td>77,201</td>
<td>17.5%</td>
</tr>
<tr>
<td>Power Mobility Devices</td>
<td>30,740</td>
<td>7.0%</td>
</tr>
<tr>
<td>Pos. Airway Pressure Device</td>
<td>19,945</td>
<td>4.5%</td>
</tr>
<tr>
<td>Other</td>
<td>18,643</td>
<td>4.2%</td>
</tr>
<tr>
<td>Nebulizers &amp; Drugs</td>
<td>14,631</td>
<td>3.3%</td>
</tr>
<tr>
<td>Hosp Bed &amp; Support Surfaces</td>
<td>13,228</td>
<td>3.0%</td>
</tr>
<tr>
<td>Enteral/Parenteral Nutri.</td>
<td>12,266</td>
<td>2.8%</td>
</tr>
<tr>
<td>Miscellaneous DMEPOS</td>
<td>9,835</td>
<td>2.2%</td>
</tr>
</tbody>
</table>
Reconsideration Appeal Results

The numbers....

- 389,390 DME claims appealed to Reconsideration
- 33,098 claims fully favorable (8.5%)
Reconsideration Appeal Results

RAC Reconsiderations

- 84.9% Unfavorable
- 15.0% Partially Favorable
- 0.1% Favorable

ZPIC Reconsiderations

- 89.9% Unfavorable
- 5.6% Partially Favorable
- 4.5% Favorable
Reconsideration Appeal Results

2013 Reconsideration Timeliness

Note: Generally, reconsiderations must be issued within 60 days of the request for appeal.
Appeals – Do They Work?

- FY 2013 Statistics Summary
  - Only approximately 2.9% of the denials were appealed (3.2 million Part B redeterminations – all Part B, not just DME)
  - Total Denied Claims:
    - 11,000,000 claims denied
    - 406,730 claims approved through Reconsideration (3.6%)
  - Total Appealed Claims:
    - 1,358,662 DME claims appealed
    - 406,730 claims approved through Reconsideration (29.9%)
### ALJ Statistics

- ALJ statistics varied with CMS participation – 2011-12 statistics
  - When **DMAC and/or QIC** participated in the appeal hearing, only **30%** of DME claims were found favorable for the supplier
  - Without DMAC and/or QIC participation in the appeal hearing, 58% of DME claims were found favorable for the supplier compared to 53% of overall claims
  - FY 2014 36.7% total appeals favorable (all types), and FY 2015 currently at 42.6%

**Note:** All 4 DMACs hired Associate Medical Directors for the sole purpose of attending ALJ hearings and defending denials

- RACs are being encouraged to defend denials throughout hearing process
- OIG criticized ALJ process due to high overturn rate, prompting changes
Focus on Compliance – A Solution, or Merely a Stopgap to Appeals?
Corporate Compliance: An Overview

- Health care reform and other federal / state regulatory initiatives have put increasing pressure on health care providers to increase compliance efforts.
- Enforcement has become more personal; no longer limited to corporate liability for non-compliant conduct.
- An effective compliance program that adds value to an organization requires both written policies and well-informed, motivated people, *not one or the other*. 

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Corporate Compliance: An Overview

- An organization’s compliance program has two fundamental purposes:
  - To ensure that all individuals in the organization observe pertinent laws and regulations in their work; and
  - To articulate a broader set of aspirational standards that are well understood within the organization and can become a practical roadmap for individuals in the organization making decisions.

- Adequate resources must be dedicated to an organization’s compliance program in order to make it work.

- The organization also must cultivate a “culture of compliance”.

- *One size does not fit all!*
Corporate Compliance Programs: Building Organizational Support

- Corporate compliance programs provide various benefits:
  - Can sensitize employees of an organization to areas of concern and clarify what constitutes permissible and impermissible conduct
  - Can help to avoid problems through use of compliance policies and training
  - Can identify potential problems early enough for senior management of an organization to move proactively to introduce corrective measures
  - Can mitigate adverse consequences of non-compliant behavior, by influencing prosecutorial discretion in how to address corporate misconduct
  - Can reduce severity of penalties at sentencing (U.S. Sentencing Guidelines)
Even if a court does not follow the U.S. Sentencing Guidelines, the existence of an effective compliance program will be relevant to a court’s consideration of an appropriate sentence under 18 U.S.C. § 3553(a), under which a court must consider, among other things:

- “[T]he nature and circumstances of the offense and characteristics of the被告”
- “[T]he need for the sentence imposed:
  - (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;
  - (B) to afford adequate deterrence to criminal conduct;
  - (C) to protect the public from further crimes of the defendant; and
  - (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.”
Corporate Compliance: Building Support Through Sources of Authority

Sources of authority for operating an effective compliance program include:

- U.S. Sentencing Guidelines
- Case Law
- DHHS OIG Industry Guidances / Workplans
- Corporate Integrity Agreements
- CMS (specifically for Medicare / Medicaid providers)
- Relevant federal and state laws (e.g., licensure, privacy)
- Industry surveys and best practices (e.g., Health Care Compliance Association, Society of Corporate Compliance and Ethics)
Elements of an Effective Compliance Program

DHHS Office of Inspector General Compliance Program Guidances

- OIG has developed a series of voluntary compliance program guidances directed at various segments of the health care industry

- OIG compliance program guidance exists for:
  - Hospitals, home health agencies, clinical laboratories, and third party medical billing companies (1998); DMEPOS suppliers, hospice providers, and Medicare+Choice organizations (1999); nursing facilities and individual physicians / small group practices (2000); ambulance suppliers and pharmaceutical manufacturers (2003); and recipients of PHS Research Awards (2005)
  - Supplemental guidance exists for hospitals (2005) and nursing facilities (2008)

- In these guidances, OIG identifies seven fundamental elements to an “effective” compliance program based on the U.S. Sentencing Guidelines
Elements of an Effective Compliance Program

The Federal Sentencing Guidelines
U.S. Sentencing Commission
Guidelines Manual § 8B2.1

- The Guidelines define an “effective” compliance program as one that is “reasonably designed, implemented and enforced so that the program is generally effective in preventing and detecting criminal conduct”

- The Guidelines outline seven elements recognized by the government as fundamental to an “effective” compliance program
Elements of an Effective Compliance Program

- ELEMENT 1 – Standards, Policies, and Procedures
- ELEMENT 2 – Compliance Governance Infrastructure
- ELEMENT 3 – Background / Exclusion / Debarment Checks
- ELEMENT 4 – Training and Communication
- ELEMENT 5 – Reporting, Monitoring, and Auditing
- ELEMENT 6 – Incentives and Disciplinary Actions
- ELEMENT 7 – Response and Prevention
Compliance Efforts to Improve Performance and Mitigate Risk

- “Real word” issues with compliance and mitigating risk
  - Completing a baseline review
  - When and what to document
  - Establishment of benchmarks and metrics for ongoing reviews
- Becoming a *partner*, not the police
  - Addressing “wink, wink, nod, nod” behavior
  - Looking into “established” behaviors and making necessary changes
- Creating an avenue to handle questions and provide appropriate answers
- Ensuring appropriate response to discovered issues
Risks of Non-Compliant Behavior: Obligations to Refund Overpayments

- Section 6402 of ACA added Section 1128J to the Social Security Act
  - Requires any provider or supplier to report and return any overpayment to the Secretary, a State, or a contractor, as appropriate; and to “notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.”

- Overpayments must be returned and notices sent no later than (1) 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable

- Any overpayment retained after the 60-day deadline is deemed to be an “obligation” under the federal False Claims Act (FCA), which may trigger FCA liability

- Providers potentially liable for civil monetary penalties for knowingly failing to report / return overpayments
Risks of Non-Compliant Behavior: Expanded OIG Audit Powers

- Section 6408 of ACA amended Section 1128A of the Social Security Act
  - Failing to grant timely access, upon reasonable request, to OIG-HHS for audits, investigations, evaluations, or other statutory functions
  - Penalty: $15,000 for each day plus assessment of not more than 3 times the amount claimed

- Section 6402 of ACA added Section 1128J to the Social Security Act
  - In order to “protect[] the integrity of the programs under titles XVIII and XIX” the OIG may obtain information from any entity or individual that
    - Is a provider of medical or other items or services; a supplier, grant recipient, contractor or subcontractor; or
    - Directly or indirectly provides, orders, manufactures, distributes, arranges for, prescribes, supplies or receives medical or other items or services payable by any Federal health care program, regardless of how the item is paid for, or to whom such payment is made
  - OIG may also obtain any supporting documentation necessary to validate claims for Medicare and Medicaid, including physician records
Risks of Non-Compliant Behavior

- **Pre-Payment Audits**
  - Audits can range from low % to 100% of claims submitted for specified HCPCS

- **Post-Payment “Fraud” Audits**
  - ZPICs / PSCs
  - SMRCs

- **Payment Suspension**

- **Exclusion from Medicare**
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