



Part D Appeals

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Presentation Overview

- Key features of Part D appeals process
- Important policy issues & clarifications
- Level 2 appeals data
- Resources
- Questions

Part D Appeals Process

- Coverage determination

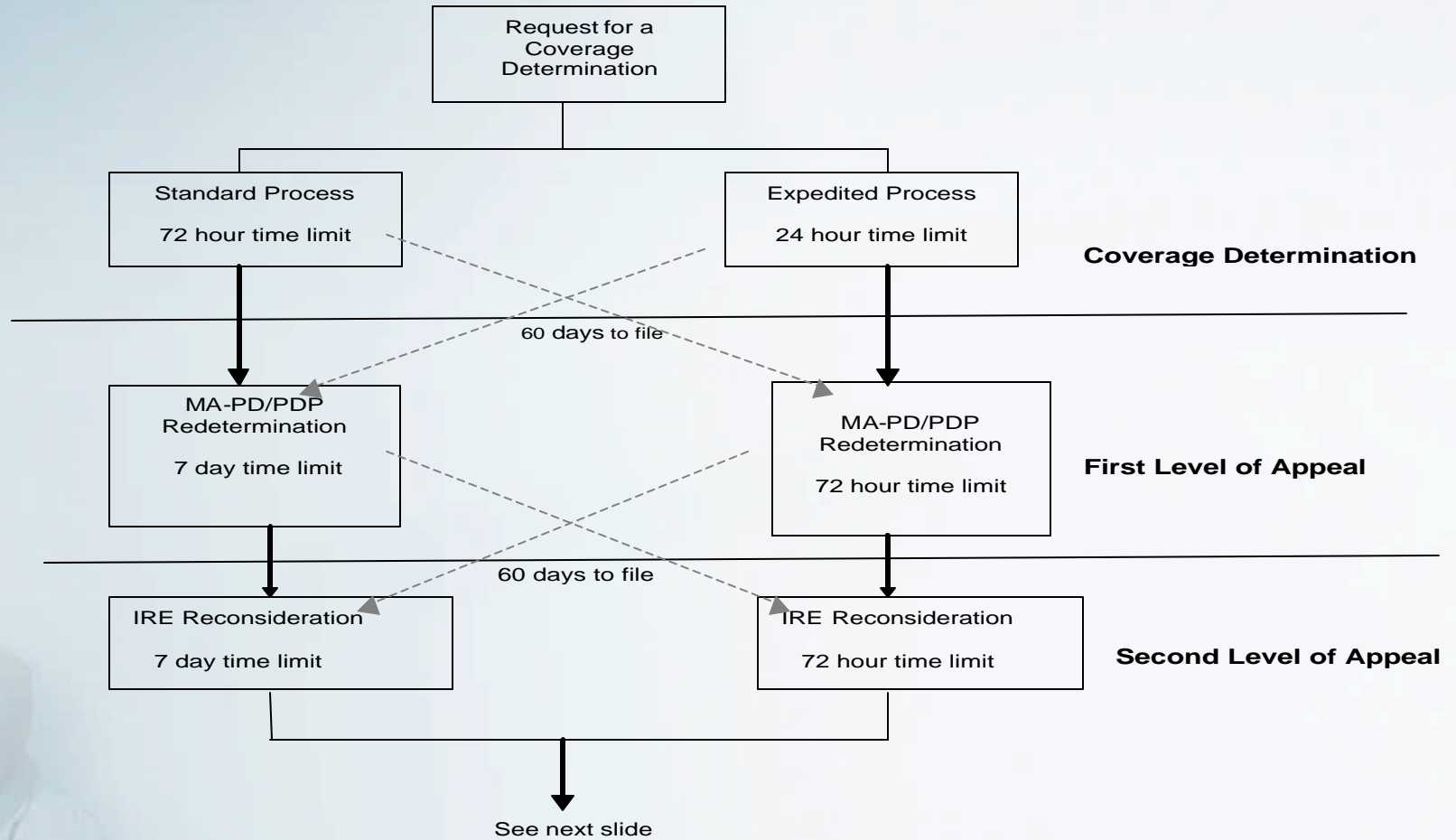
Initial decision by plan about:

- Benefits an enrollee is entitled to receive
- Amount an enrollee is required to pay

Coverage determinations include:

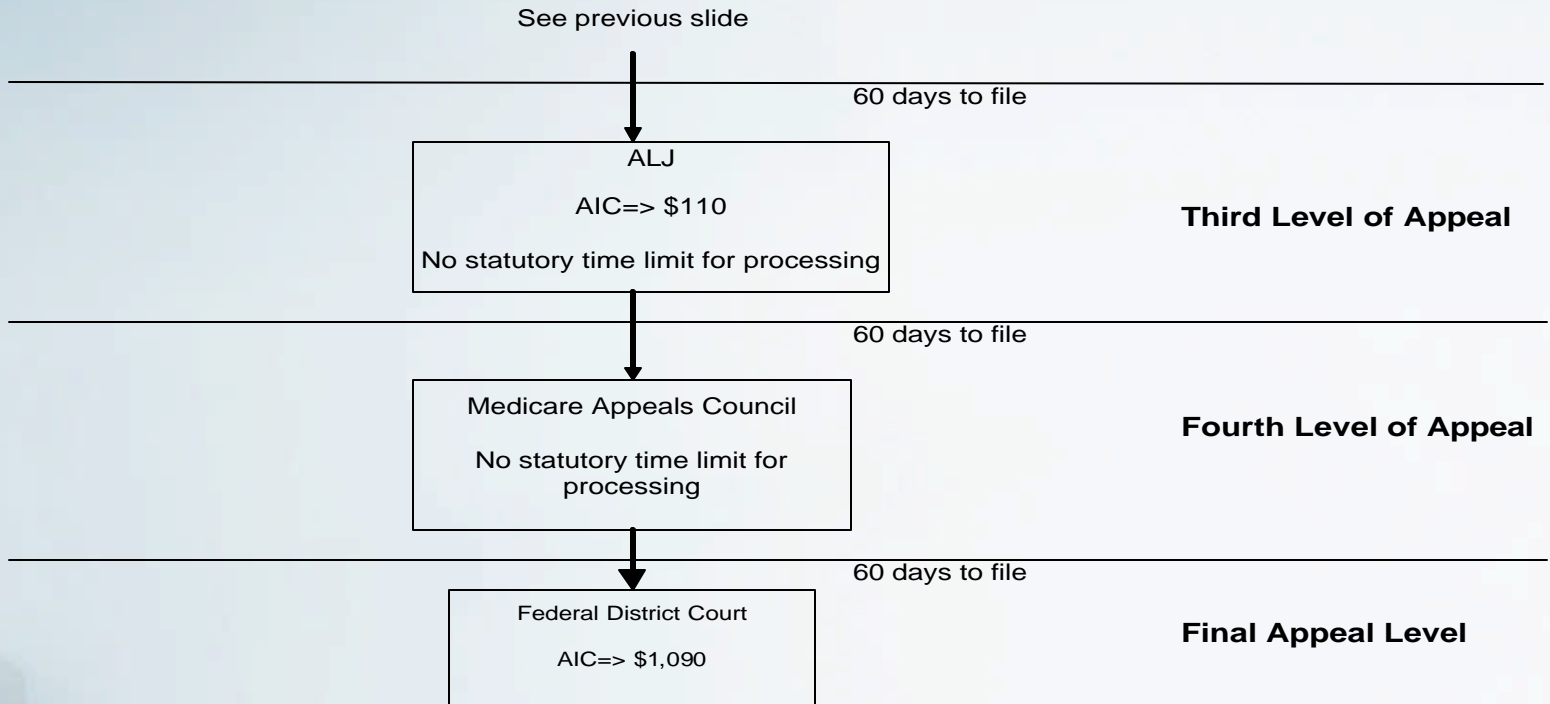
- Exception requests (off-formulary/Drug Utilization Management & tiering)
 - Request for a drug that has a prior authorization requirement
- 5 step appeals process

Coverage Determination & Appeals Process



IRE = Independent Review Entity
 MA-PD = Medicare Advantage plan that offers Part D benefits
 PDP = Prescription Drug Plan

Coverage Determination & Appeals Process (continued)

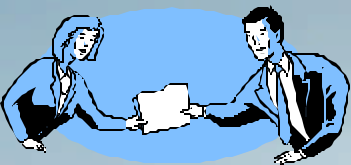


AIC = Amount in controversy
ALJ = Administrative Law Judge



Part D Adjudication Timeframes

- Plans must notify enrollee of decision as expeditiously as enrollee's health requires, but no later than regulatory timeframes
- Coverage determinations – 24/72 hours
clock starts upon receipt of request; if an exception request, upon receipt of prescribing physician's supporting statement
- Redeterminations – 72 hours/7 days
- Reconsiderations – 72 hours/7 days



Auto-forwarding Cases

- If plan misses adjudication timeframe, must forward complete case file to Part D Qualified Independent Contractor (QIC) w/in 24 hours
- Examples of improper auto-forwarding:
 - timeframe has not lapsed (supporting statement has not been received for an exception request)
 - plan has issued a fully favorable decision just outside applicable timeframe
 - these cases will be dismissed by the Part D QIC

Prescribing Physicians



- When can a prescribing physician act on behalf of an enrollee?
 - Coverage determinations (expedited & standard)
 - Redeterminations – expedited *only*
- For all other appeals, must be enrollee's appointed representative (Form CMS-1696 or equivalent written instrument or authorized per state law)
- Auto-forwarded cases – if physician requested c/d or expedited redetermination, Part D QIC can proceed with case/no AOR needed

Drug Utilization Management Tools

- Confusion about how to process coverage determinations when requested drug subject to Prior Authorization (PA) or other UM requirement
- Process as:
 - (1) “routine” coverage determination *or*
 - (2) an exception request
- Ask: Is enrollee/physician:
 - (1) attempting to satisfy requirement *or*
 - (2) making the case that the PA or other UM requirement shouldn't apply for reasons of medical necessity?

Drug Utilization Management Tools

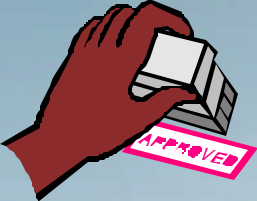
cont'd

- If physician/enrollee has indicated that enrollee can't satisfy requirement, should be processed as an exception request; prescribing physician supporting statement needed
- If physician/enrollee attempting to satisfy requirement (e.g., completion of PA form, submission of certain lab results), process as "routine" coverage determination request
- Usual timeframes apply
- Plans should make PA forms readily accessible



Model Forms

- Coverage Determination Request Forms
 - Enrollee version
 - Prescribing physician version (Exception & PA Request Form)
- “Request for Prescription Information or Change”
 - Facilitates pharmacist to physician communication
- Reconsideration Request Form
 - Plans must send w/ adverse redetermination decisions
 - Helps enrollee request level 2 appeal
 - Ensures Part D QIC receives needed information quickly (e.g., Medicare #, plan name)



Approved Exception Requests

- If exception is approved, it is valid for remainder of plan year if
 - individual remains enrolled in plan
 - physician continues to prescribe drug
 - remains safe for treating enrollee's condition
- Plan may continue coverage under the approved exception into subsequent plan year



Approved Exception Requests *cont'd*

- If plan does not continue into subsequent plan year, must provide enrollee with written notice at time exception is approved or 60 days before the end of the plan year that coverage under the approved exception will terminate at the end of the plan year
- Affords enrollee w/ opportunity to make new request to avoid coverage gaps

Policy Clarification

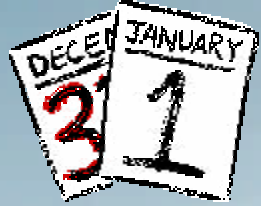
Quantity Limits

- Statutory definition of Part D drug – “medically accepted indication” per FDA labeling or use supported by compendia
- Plans may have dose limitations based on FDA labeling
- Clarification: “*Medically accepted indication*” does not include the dose prescribed for the individual
- Enrollee may request (and be granted) an exception to a dose limitation through the formulary exception process based on medical necessity criteria

Policy Clarification

Cough/cold medicine exclusion

- Statute excludes coverage for “agents when used for the symptomatic relief of cough and colds.”
- Clarification: not a blanket exclusion
- Cough/cold medications may meet definition of a Part D drug if being used for other than symptomatic relief of cough/cold
- Examples of clinically relevant situations: to reduce risk of broken bones in patient with severe osteoporosis; when uncontrolled cough is exacerbating another condition – SOB in patient with severe asthma



End of Plan Year Issues

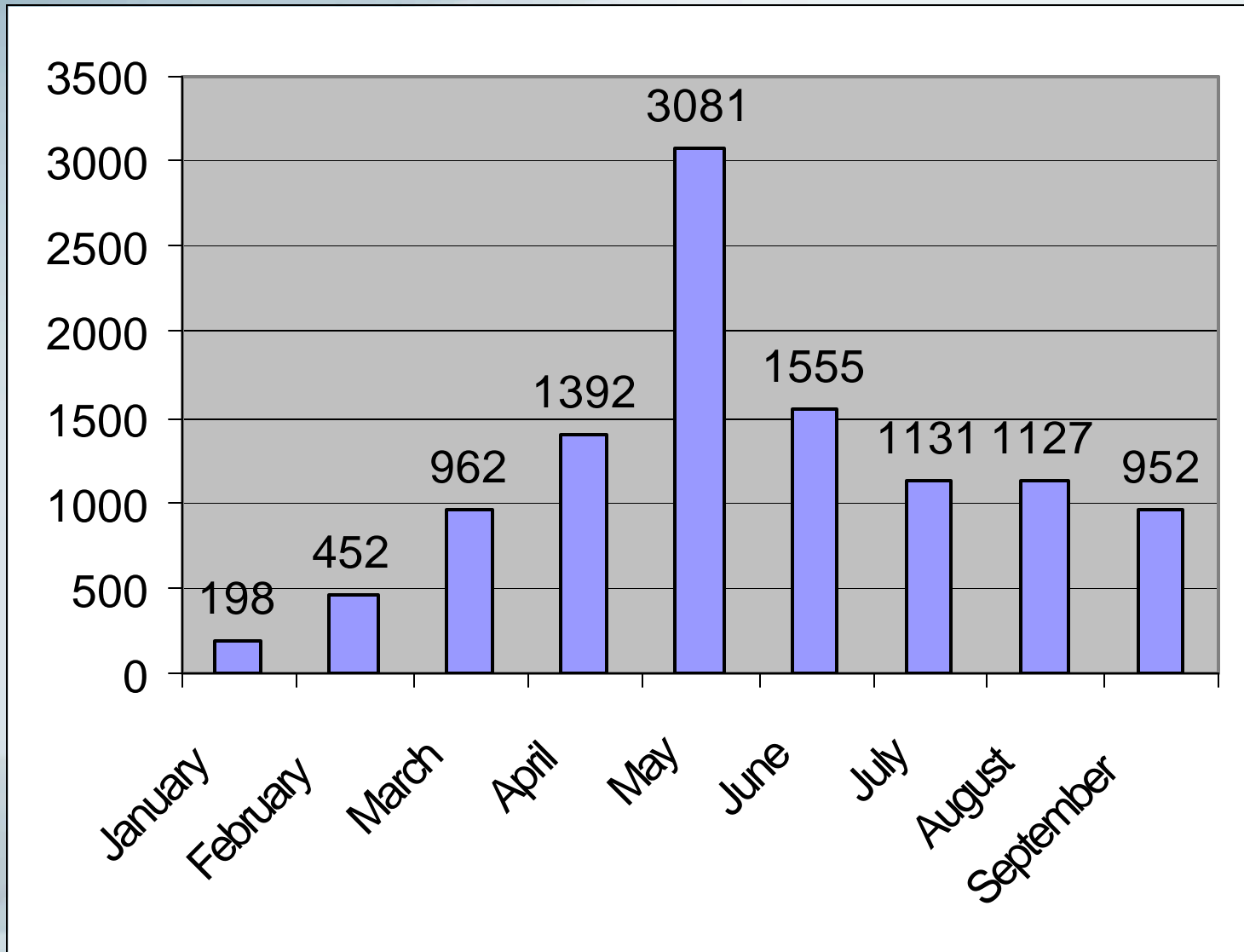
- For enrollees who remain in plan but experience negative formulary changes (e.g., drug in current regimen will be off-formulary for 2007) or who have an approved exception that will expire at end of year, plans expected to:
 - (1) provide temporary supply of drug per 2007 Formulary Transition Guidance and notify enrollee that s/he must switch to formulary drug or request exception or
 - (2) prospectively process exception requests under new formulary and approve/authorize payment prior to 1/1/07 and provide coverage beginning 1/1/07
- Plans should work with enrollees/physicians to avoid coverage gaps

Part D Reconsideration Data*

- Part D Reconsideration Appeals Data Fact Sheet: <http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/ReconAppealsData.pdf>
- 10,850 reconsideration requests received by Part D QIC through September 2006
- 37% of all cases received by Part D QIC were auto-forwarded by plans
- Appeal Types:
 - 37% - DUM tool dispute
 - 36% - Off-formulary request
 - 23% - Non-Part D drug request
 - 2% - Cost sharing
 - <2% - Tiering exception
 - <1% - Out-of-network

*Based on data reported by Part D QIC in October workload reports

Reconsiderations Received by Month



Resources

- New Appeals Website:
<http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/>
- Chapter 18 – Prescription Drug Benefit Manual:
<http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/PartDManualChapter18.pdf>
- Model Coverage Determination Request Forms:
<http://www.cms.hhs.gov/center/provider.asp>

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