Medical Necessity –

Current Status, Key Best Practices in Prevention of Medical Necessity Denials and Recoupments

With the establishment of the Affordable Care Act, Recovery Audit Contractors (RACs), and increased surveillance by the Office of Inspector General (OIG), "medical necessity" has become a key, and sometimes feared, buzzword for healthcare providers. The term broadly governs numerous aspects of healthcare and can present challenges in billing, reimbursement, and compliance.

Since the mid-1970s,[1] Medicare has identified medical necessity as a potentially problematic area. In 1986, Congress required that healthcare providers ensure that services or items furnished: "**(1)** will be provided economically and only when, and to the extent, medically necessary; **(2)** will be quality services which meet professionally recognized standards of healthcare; and **(3)** will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities."[2]

And it is with such stringent documentation requirements set forth by the Centers for Medicare & Medicaid Services (CMS) that providers often find their greatest challenges.

Medical Necessity Directives

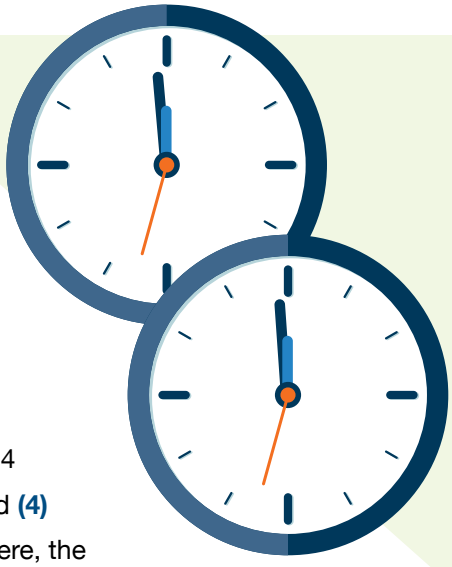
When we refer to medical necessity, we may be using the term in a variety of contexts. As it relates to an inpatient or outpatient hospital setting, medical necessity generally refers to the documentation of services rendered along with the need for those services. Clinical medical necessity encompasses the presence of unique concepts and guidelines in order that it might be considered appropriate. As it relates to payer reimbursement, medical necessity deals with physician documentation of the signs, symptoms, and treatment supporting the rationale for coverage as described above.

Clinical medical necessity for hospital admission is determined through the review of documentation provided by the physician, emergency medical assistants, emergency nurses and physicians, and others who have provided information regarding the patient's preadmission presentation. Clinical criteria, such as InterQual and MCG (formerly Milliman Guidelines), are used by non-physicians to screen for appropriateness of admission.

For many years, Case Managers (CM) and Utilization Review (UR) nurses were thought to be the admissions gatekeepers; if the patient documentation met the criteria used by the hospital, the CM or UR nurse would interact with the physician to convey that the patient was meeting inpatient status.

1 *Medicare Amendments of 1979: Report of the Committee on Ways and Means, U.S. House of Representatives, to Accompany H.R. 4000,* The Centers for Medicare & Medicaid Services, November 1979.

2 *Medicare and Medicaid Patient and Program Protection Act of 1986: Report (to Accompany H.R. 1868),* The Centers for Medicare & Medicaid Services, October 1986.



However, October 1, 2013, CMS established the Two-Midnight Rule, which clarified physicians would make decisions with regard to admission status. The rule attempted to provide guidelines for physicians when deciding whether to admit a patient as inpatient or in an observation/outpatient setting. It stated that, "Factors to be considered when making the decision to admit include such things as: **(1)** the severity of the signs and symptoms exhibited by the patient; **(2)** the medical predictability of something adverse happening to the patient; **(3)** the need for diagnostic studies that appropriately are outpatient services (*i.e.*, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and **(4)** the availability of diagnostic procedures at the time when, and at the location where, the patient presents."[3]

Yet, when the Two-Midnight Rule was implemented, there was concern it limited the practice and admission abilities of physicians and hospitals. During an initial "probe and educate" period, CMS temporarily suspended penalties for misusing and misunderstanding the rule.[4]

A new directive, the Medicare Outpatient Observation Notice (MOON), was issued in January 2017 and implemented February 21, 2017. It was developed to inform all Medicare beneficiaries, both "Original Medicare (fee-for-service) and Medicare Advantage enrollees,"[5] whether they are deemed outpatients receiving observation services, as opposed to inpatients of the hospital or critical access hospital (CAH). Notification must be given to Medicare beneficiaries who have received outpatient observation services for more than 24 hours. MOON must be provided in the form of written and oral instructions no later than 36 hours after the commencement of observation services. And such notification should be provided to any person with Medicare benefits, including beneficiaries with Part A coverage, but not Part B, who are subsequently admitted as inpatient but started under observation status, as well as beneficiaries with both primary and/or secondary Medicare coverage.

Other directives available for determining medical necessity include National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). NCDs describe whether specific medical items, services, treatments, procedures, or technologies can be paid for by Medicare and can describe indications that are covered,

3 *CMS Manual System, Pub 100-02 Medicare Benefit Policy, Transmittal 232, The Centers for Medicare & Medicaid Services, December 2016,* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R232BP.pdf, accessed on March 24, 2017.

4 "Fact Sheet: Two-Midnight Rule," July 2015, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-07-01-2.html, accessed on March 24, 2017.

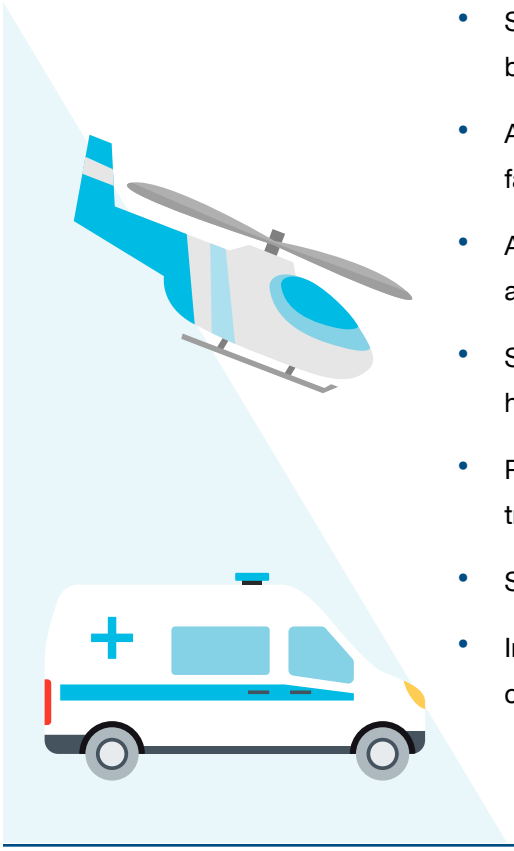
5 *Medicare Claims Processing Manual, The Centers for Medicare & Medicaid Services, January 2017, Chapter 30, "Financial Liability Protections,"* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf, accessed on March 24, 2017.

not covered, or both. Per the NCD Manual, an NCD does not restrict coverage unless it contains a statement explicitly excluding coverage. Where coverage for an item or service is provided for specified indications or services, but not explicitly excluded for others, or where the item or service is not mentioned at all, the local Medicare Administrative Contractor (MAC) has the discretion to make coverage decisions, in consultation with its medical staff and with CMS when appropriate, based on the law, regulations, rulings, and general program instructions.[6]

Similarly, local MACs develop coverage determinations to further clarify NCDs, or make their own LCDs, based on discretion, for services or items that are not addressed in the NCD Manual. LCDs often contain greater coding details, such as specific diagnosis codes that must be present for payment, or certain codes that are used at the local contractor's discretion.

Technical Denial

A technical denial of payment by Medicare stems from a failure to meet coverage requirements and can be comprised of several different factors. Some of these factors include, but are not limited to, failure to meet a condition of payment required by regulations which have been defined in an NCD, LCD, or other regulatory decisions. Each healthcare service has specific regulations and Conditions of Participation (CoPs) which set forth the minimum standard requirements to participate in the Medicare program. Failing to adhere to the CoP is considered a technical denial. In the past, appeals and overturned decisions for technical denials have been difficult to win. Some other areas which lead to technical denials include:



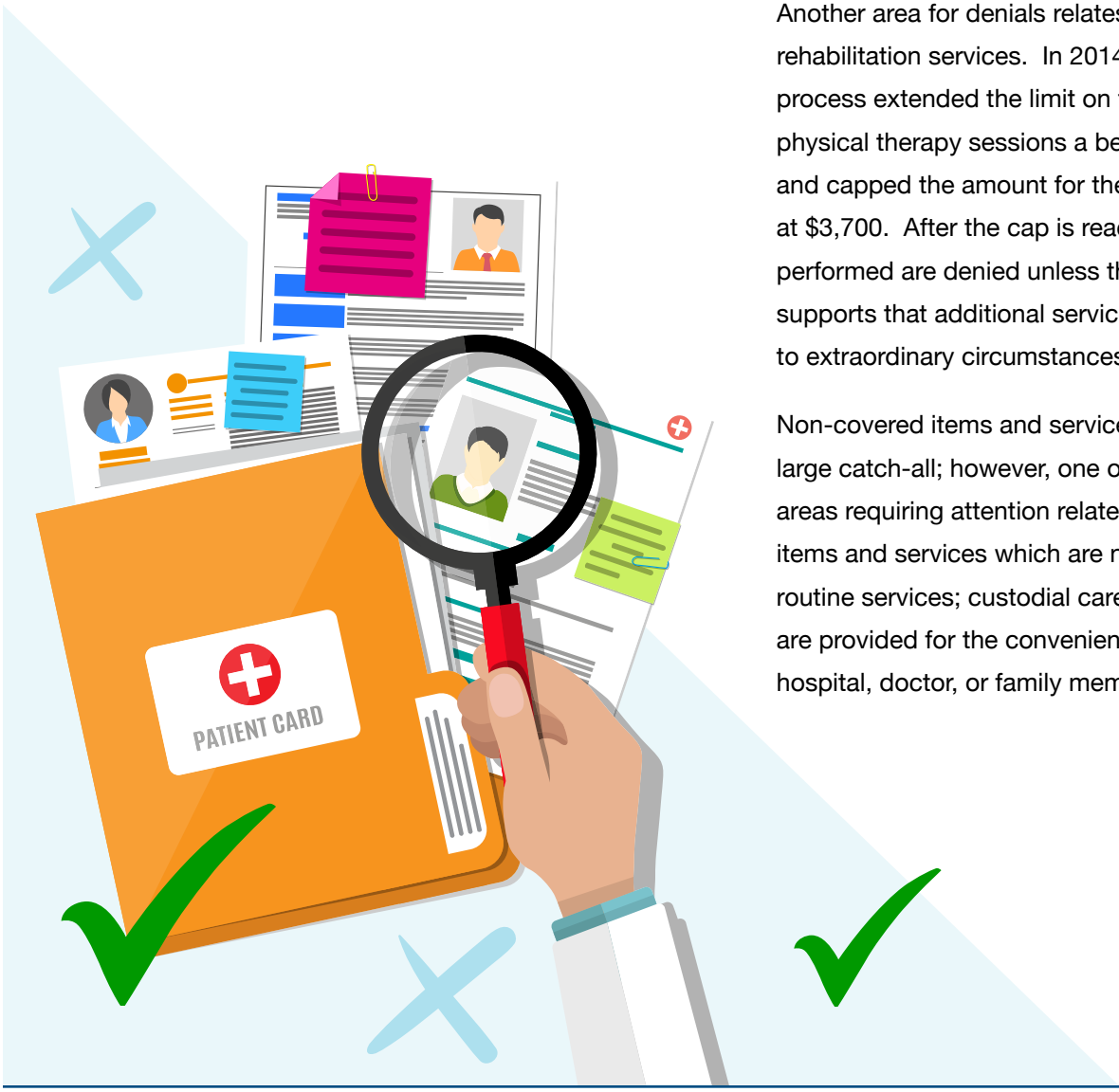
- Self-administered drugs, which are usually in oral form and can be taken by the patient without the assistance of a nurse or skilled personnel.
- Ambulance services, such as transport from a hospital to a skilled nursing facility (SNF) when the patient is not bedridden.
- Air ambulance services when the medical record supports the use of safe and effective ground transportation for the patient.
- SNF admission not preceded by the required three-day inpatient hospitalization.
- Payment for home health services that were not ordered on a plan of care treatment or subsequent amendment.
- Services that do not meet all qualifying requirements for NCDs and LCDs.
- Incorrect code selection or insufficient documentation to support the code billed.

6 *Medicare National Coverage Determinations Manual, The Centers for Medicare & Medicaid, May 2016, Chapter 1,* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf, accessed on March 24, 2017.

Categorically Excluded Services

Medicare identifies four categories of items and services that are not covered under the Medicare program:[7] **(1)** those that are not medically reasonable and necessary; **(2)** non-covered items and services identified specifically by CMS; **(3)** those denied as bundled or included in the basic allowance of another service; and **(4)** those reimbursable by other organizations or furnished without charge.

Inpatient Rehabilitation Facility (IRF) services comprise another facet of care receiving notice of audits for medically unnecessary services. Denials have been based on the fact that the services provided constituted activities of daily living (ADL). Often, patients have either suffered a stroke or spent an extended period of time in the hospital and need IRF to get back to their pre-illness baseline for ADL, or to establish a new baseline for ADL.



Another area for denials relates to outpatient rehabilitation services. In 2014,[8] an exception process extended the limit on the number of physical therapy sessions a beneficiary can have and capped the amount for therapy services at $3,700. After the cap is reached, services performed are denied unless the documentation supports that additional services were required due to extraordinary circumstances.

Non-covered items and services are considered a large catch-all; however, one of the more important areas requiring attention relates to personal comfort items and services which are not covered, including routine services; custodial care; and services that are provided for the convenience of the patient, hospital, doctor, or family members.

7 *Items and Services That Are Not Covered Under the Medicare Program, The Centers for Medicare & Medicaid Services, January 2017,* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Items-and-Services-Not-Covered-Under-Medicare-Booklet-ICN906765.pdf, accessed on March 24, 2017.

8 "Therapy Cap: Manual Medical Review of Therapy Claims above the $3,700 Threshold," February 2016, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html, accessed on March 24, 2017.

Bundled Services

Medicare traditionally makes separate payments to the provider for each course of treatment and single illness.[9] The Center for Medicare & Medicaid Innovation (CMMI) developed four models of care that link payments for multiple services and providers with the intention of providing seamless care transition.

As stated by CMMI, "The Bundled Payments for Care Improvement initiative is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care."[10]

	Model 1	Model 2	Model 3	Model 4
Episode	All Diagnostic-Related Groups (DRGs); all acute patients	Selected DRGs; hospital plus post-acute period	Selected DRGs; post-acute period only	Selected DRGs; hospital plus readmissions
Services included in the bundle	All Part A services paid as part of the MS-DRG payment	All non-hospice Part A and B services during the initial inpatient stay, post-acute period, and readmissions	All non-hospice Part A and B services during the post-acute period and readmissions	All non-hospice Part A and B services (including the hospital and physician) during initial inpatient stay and readmissions
Payment	Retrospective	Retrospective	Retrospective	Prospective

Model 1 began in April 2013 and concluded March 31, 2016. In Model 1, the inpatient stay in the acute care hospital was the only affected service. Medicare retrospectively paid the hospital a discounted payment rate from the Inpatient Prospective Payment System used in the original Medicare program. Physicians were paid separately for their services under the Medicare Physician Fee Schedule.

In Models 2 and 3, Medicare continued to pay providers and service suppliers a fee-for-service payment for a range of services, including acute care (hospital stay) and post-acute care (SNF, IRF, home health, and long-term care hospitals). However, at the time of reconciliation, the total expenditures for all services under the DRG for that episode of care were reconciled against the bundled payment amount or target price, which was determined by CMS. The recoupment from those not meeting target price was recovered and the award for meeting the target paid.

In Model 4, CMS paid a prospectively determined, single bundled payment to the hospital, which thereby pays all providers. This included payment for all services furnished by the hospital, physicians, and other practitioners during that entire inpatient stay.

Models 2, 3, and 4 were implemented in two phases. During the first phase, CMS worked with the participating facilities and their partners. During phase two, the performance period was implemented, and all participants were in the risk period.

9 "Bundled Payments for Care Improvement Initiative (BPCI)," April 2016, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-18.html, accessed on March 24, 2017.

10 "Therapy Cap: Manual Medical Review of Therapy Claims Above the $3,700 Threshold," April 2014, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html, accessed on March 24, 2017.

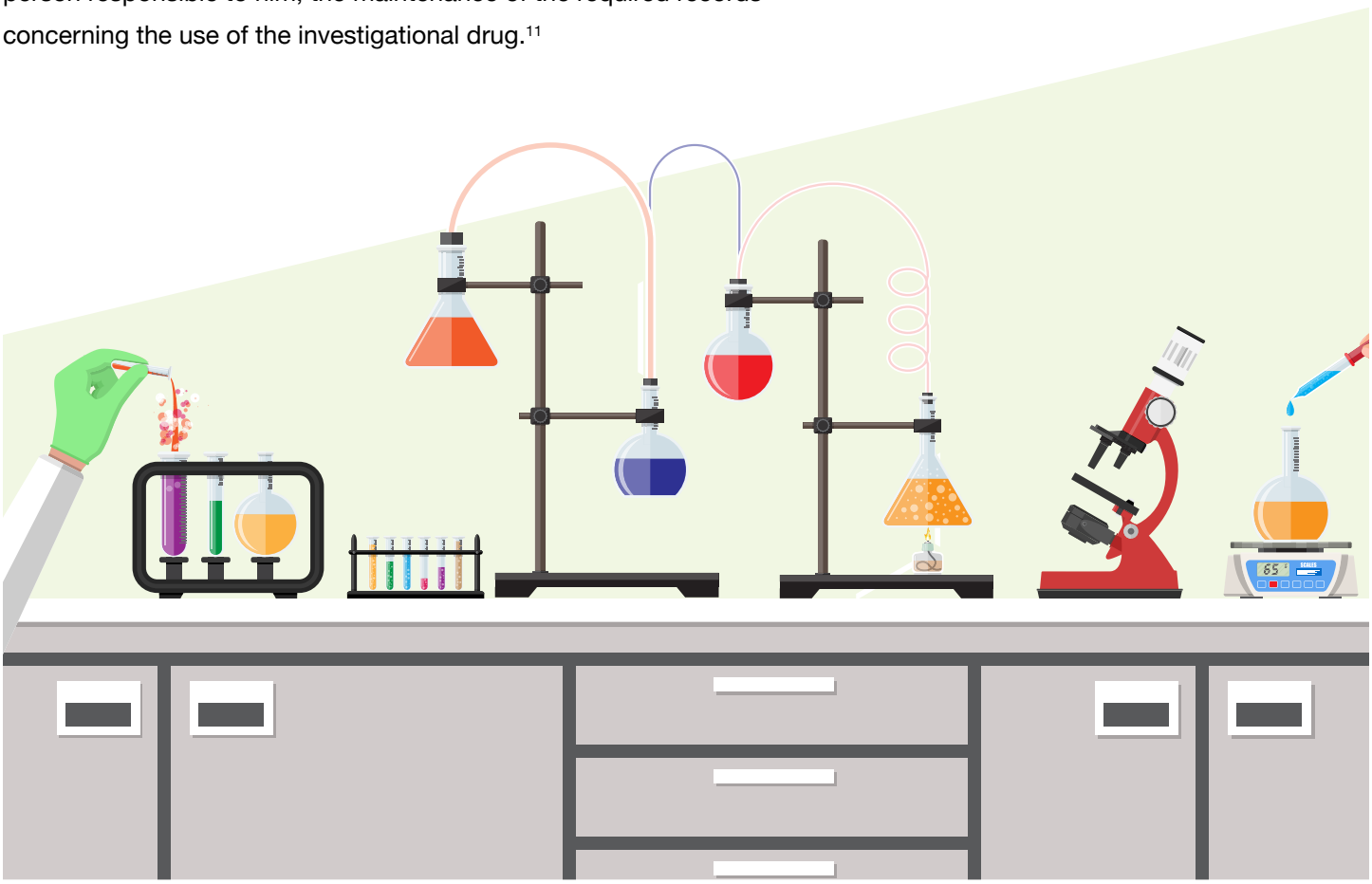
Investigational Drugs

The Federal Food and Drug Administration (FDA), part of the Department of Health and Human Services, states in Section 510 of the Federal Food, Drug, and Cosmetic Act, that preparation of investigational drugs by a hospital pharmacy for use by an investigator in the hospital or in another hospital requires registration. However, if the new drug has been, or will be, shipped in interstate commerce for clinical trials, the sponsor of the investigation should file a "Notice of Claimed Investigational Exemption for a New Drug" before the shipment is made or the trials begin. This notice would provide information regarding manufacture of the new drug by the pharmacy and include the pharmacy's name and address.

The submission of Forms FD-1571, 1572, and 1573 is only required when the finished new drug, or the "new drug substance" used in its manufacture, is in interstate commerce.

When interstate commerce is involved, and the various forms are required for submission, the hospital or its designee may act as the "sponsor" and file Form FD-1571. Such a "sponsor" should obtain completed Form FD-1572 or 1573, as appropriate, from the actual investigators.

The physician-investigator may delegate to a hospital pharmacist responsible to him, or any other person responsible to him, the maintenance of the required records concerning the use of the investigational drug.[11]



11 "CPG Sec. 460.100 Hospital Pharmacies – Status as Drug Manufacturer," U.S. Food & Drug Administration, October 1980, https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074397.htm, accessed on March 24, 2017.

Current federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. The Investigational New Drug application (IND) is the means through which a sponsor technically obtains FDA approval for distribution or transport across state lines to clinical investigators.

During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development.

There are three kinds of INDs:

- An Investigator IND is submitted by a physician who both initiates and investigates, and under whose immediate direction the investigational drug is administered or dispensed.
- An Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency that does not allot time for submission of an IND in accordance with 21CFR, Sec. 312.23.
- A Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories:

- Commercial
- Research (non-commercial)

The IND application must contain information relating to three areas, all of which are broad:

- Animal pharmacology and toxicology studies: Preclinical data permitting an assessment as to whether the product is reasonably safe for initial testing in humans. This information also includes any previous experience with the drug in humans (often foreign use).
- Manufacturing information: Pertains to the composition, manufacture, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical protocols and investigator information: Includes detailed protocols for proposed clinical studies to assess whether the initial phase trials will expose subjects to unnecessary risks and the provision of information regarding the qualifications of clinical investigators. Clinical investigators (CIs) are professionals, generally physicians, who oversee the administration of the experimental compound. The application information helps to assess whether the CI is qualified to fulfill his or her clinical trial duties.

Commitments to obtain informed consent from the research subjects, obtain review of the study by an institutional review board, and adhere to the investigational new drug regulations are also required. Once the IND is submitted, the sponsor must wait 30 days to begin the clinical trial.[12]

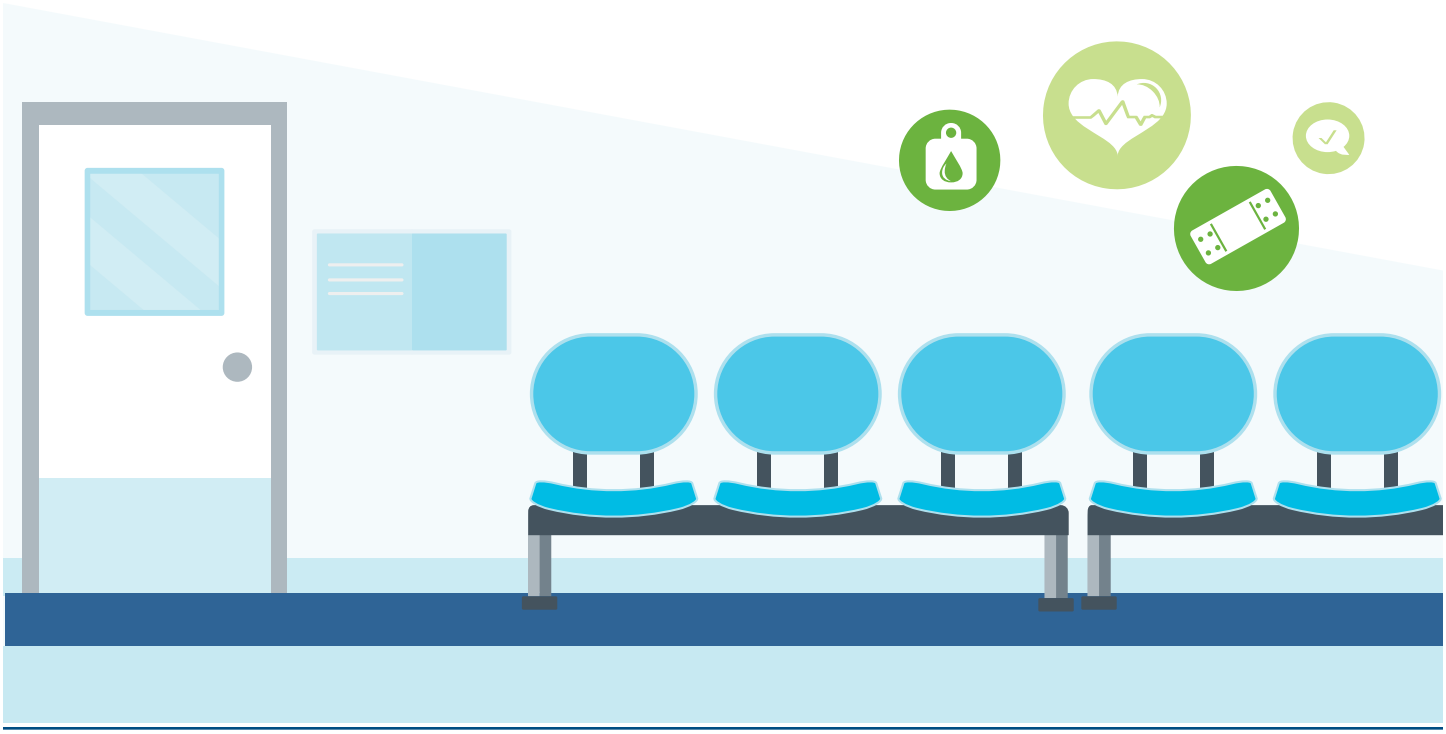
12 "Investigational New Drug (IND) Application," U.S. Food & Drug Administration, August 2016, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/, accessed on March 24, 2017.

Admission Criteria for Skilled Nursing Facilities and Inpatient Rehabilitation Services

For Medicare beneficiaries to qualify for skilled nursing care, they must have had a current three-day inpatient qualifying stay. Recently, this has come under much scrutiny and led to increased audit activities; regulations; and confusion on the part of Medicare beneficiaries and their families, hospitals, and SNFs. A three-day qualifying stay is a hospital inpatient admission that spans three midnights and excludes the day of discharge. An observation status does not meet this standard. The Medicare beneficiary must have also had, during the minimum three-day stay, a treated condition that will require a skilled service to be provided daily, post-discharge.[13] Skilled services include nursing services, such as infusion therapy or wound care, and can also include physical therapy and/or occupational therapy.

While the patient is still in the acute care hospital, a Preadmission Screening and Resident Review (PASRR) must be completed prior to admission into an SNF or long-term acute care (LTAC) facility. SNF or LTAC services should not be provided or billed without the submission of a PASRR, the details of which should also be placed on the patient chart.[14] This is a federal requirement to ensure that individuals are not inappropriately placed in nursing homes for long-term care.

The physician must declare the patient needs skilled nursing care. Specifically, the physician must include the diagnoses and skilled services required on the patient's chart upon admission, and must take into consideration economy and efficiency. The ordered daily skilled service can only be provided on an inpatient basis in an SNF.

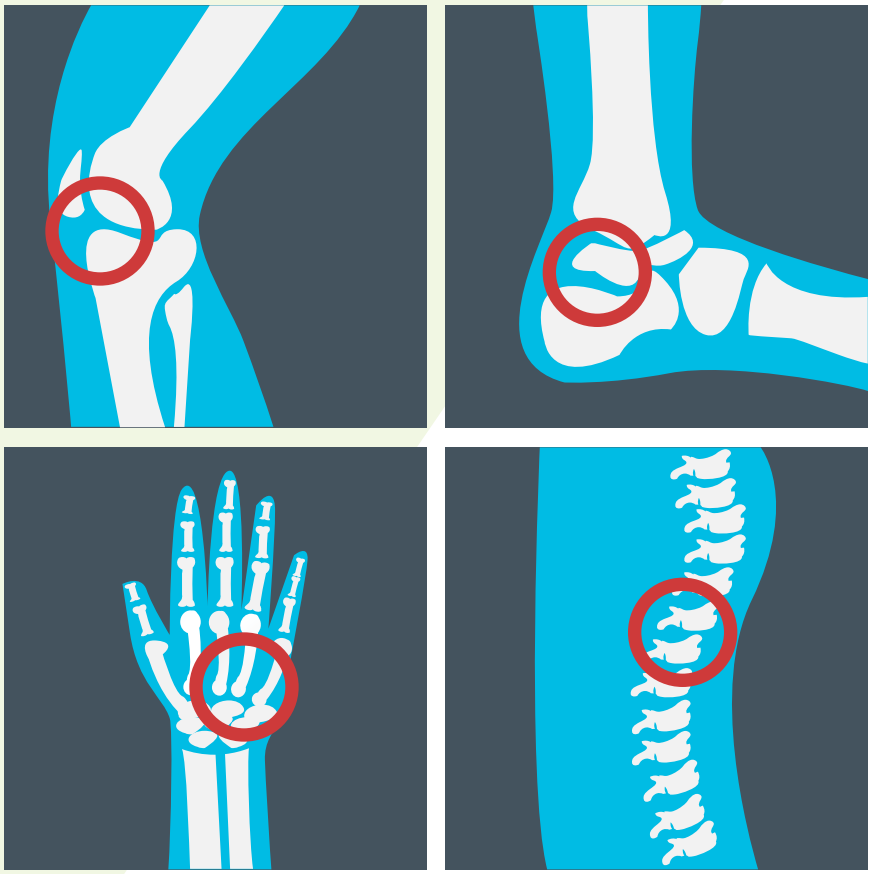


13 *Medicare Benefit Policy Manual, The Centers for Medicare & Medicaid Services, October 2016, Chapter 8, "Coverage of Extended Care (SNF) Services Under Hospital Insurance," Chapter 10, "Requirements – General," Chapter 20, "Prior Hospitalizations and Transfer Requirements," Chapter 30, "Skilled Nursing Facility Level of Care-General," Chapter 40, "Physician Certification and Recertification for Extended Care Services," Chapter 50, "Covered Extended Care Services,"* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html, accessed on March 24, 2017.

14 *Medicare Benefit Policy Manual, The Centers for Medicare & Medicaid Services, December 2016, Chapter 1, "Inpatient Hospital Services Covered Under Part A," pp. 23-24,* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf, accessed on March 24, 2017.

Once a patient is admitted, the documentation must continue to specify timeframes and requirements that must be met to prove medical necessity for the admission and stay. A Minimum Data Set is a federally mandated process for clinical assessment of all residents in Medicare or Medicaid-certified nursing homes. This process provides a comprehensive assessment of residents' functional capabilities and helps nursing home staff identify health issues.

IRFs have detailed, time-sensitive requirements which must be met for payment of a beneficiary's care—for admission and continued stay. For instance, Medicare has a list of 13 diagnoses that must be met by at least 60% of the IRF population. An admission diagnosis of debilitation, which is common with elderly hospitalized patients, is not included in the list of approved diagnoses. However, if a physician believes and documents that the patient has a high chance of attaining his or her pre-hospitalization baseline of ADL, including walking, maneuvering with a wheelchair or other assisted device, and daily hygienic practices, the patient can be deemed appropriate for IRF.

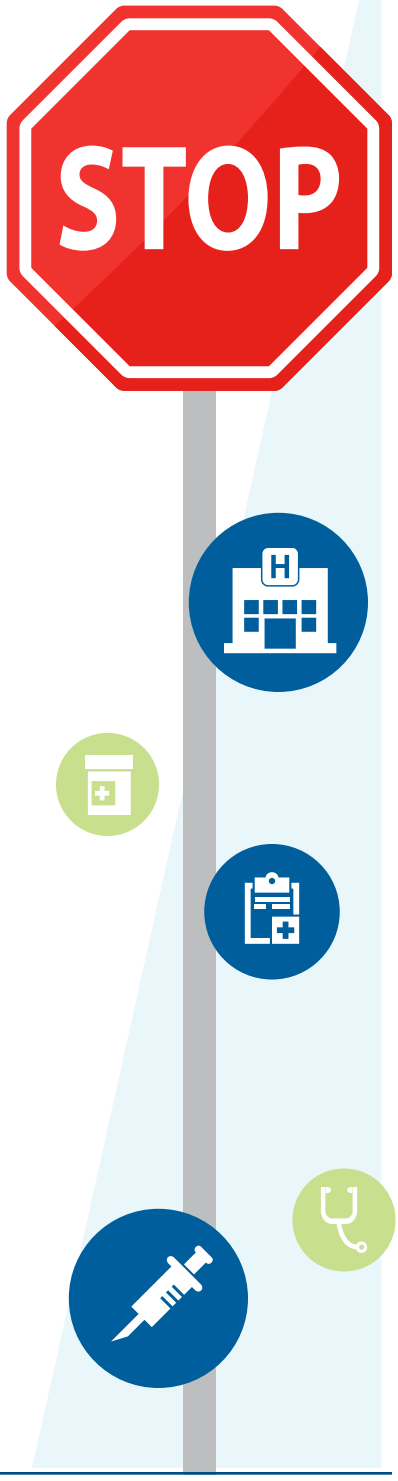


Thorough documentation is the key to payment. Some reasons for which payment for IRF services is denied include the specific timeframe requirements – for example, a lack of pre-admission screening, which is the time the patient is in the acute hospital; post-admission evaluation by the rehabilitation (rehab) specialized physician, which must occur within the first 24 hours after admission into the IRF; physician notes, which must be made every two to three days the patient is receiving care; and patient participation in rehab services, which must take place three hours per day and begin within 36 hours of admission.

It is critical that physicians document whether patients have a fair or good chance for improvement as well as set forth numbered individual goals for returning patients to their previous levels of function.

Advanced Beneficiary Notification and Hospital Notice of Non-Coverage

An Advanced Beneficiary Notification[15] (ABN) is a tool used by providers to communicate to the Medicare beneficiary that the service ordered will likely not be a covered service. This allows the beneficiary to make an informed decision regarding the service. For example, a physician may order an MRI or CT scan when an x-ray would be medically appropriate. If the physician determines that an MRI, CT, or other service is more appropriate than the less-expensive option, the physician's documentation stating the reason for this decision, the inappropriateness of other options, and the expected outcome, becomes the key factor in determining whether the service will be covered.



In addition to outpatient services, ABN services that must comply with ABN delivery include SNF, home health, durable medical equipment, and hospital.

Hospital notices are referred to as Hospital-Issued Notice of Non-Coverage (HINN) for inpatient admission. HINNs can be issued at preadmission, admission, or during a continued stay. There are specific regulations,[16] forms, and notices that must be used depending on when (*i.e.,* at what point) the patient did not meet inpatient criteria.

If the patient was appropriate for admission, but no longer requires the intensive setting of inpatient care, and the attending physician does not agree that the patient does not meet inpatient criteria, a HINN for concurrent care would be utilized to notify the patient after the requirements for Hospital Conditions of Participation are followed.

In these circumstances, the Utilization Management (UM) committee should be notified, and two members would review the medical record and speak with the attending physician to gain his/her perspective of the case. If the UM committee believes the inpatient admission or continued stay is inappropriate, a HINN would be presented and the patient advised within two days of the decision of non-coverage. The patient has the right to request a review by the Quality Improvement Organization (QIO) and will not be liable for time as an inpatient until a decision from the QIO has been received and that decision upholds the hospital's claim.

The failure of the hospital or other service providers to deliver an ABN or other notice of non-coverage will place the provider at risk for financial liability should there be a denial of the claim. It should also be noted that CMS warns against distributing blank ABNs without cause.

15 *Medicare Claims Processing Manual, The Centers for Medicare & Medicaid Services, January 2017, Chapter 30, "Financial Liability Protections,"* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf, accessed on March 24, 2017.

16 *State Operations Manual, Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, §482.30, "Condition of Participation: Utilization Review," The Centers for Medicare & Medicaid Services, November 2015,* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf, accessed on March 24, 2017.

Billing Decisions for Medically Unnecessary Services

Condition Code 44[17]

In 2004, CMS implemented a new billing code for a situation in which the additional internal review of a patient admitted as an inpatient determines that the patient does not meet inpatient criteria; therefore, observation status is most appropriate.

In cases where the UR Committee determines that the inpatient admission does not meet inpatient criteria, observations can be billed if the following steps are in place: **(1)** the change from inpatient status to observation is made prior to discharge; **(2)** the hospital has not submitted a claim to Medicare; **(3)** and the physician agrees with the UR Committee that the status should be changed.

Provider liability[18] occurs when a Medicare Part A payment cannot be made because an inpatient admission is found to be unreasonable and unnecessary, and the beneficiary should have been treated as a hospital outpatient rather than a hospital inpatient. Medicare Part B will allow payment of all performed hospital services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted to the hospital as an inpatient, except for those services that specifically require an outpatient status, provided that the beneficiary is enrolled in Medicare Part B and that the allowed timeframe for submitting claims has not expired.

This policy applies to all hospitals and CAHs participating in Medicare. For this to be founded, it must be determined that the provider had actual knowledge of the non-covered service or could have reasonably been expected to have knowledge that the service was not covered.

Self-Disclosure

The Self-Disclosure Protocol[19] (SDP) is a process for healthcare providers to voluntarily identify, disclose, and resolve instances of potential fraud involving federal healthcare programs (as defined in section 1128B[f] of the Social Security Act [the Act], 42 U.S.C. 1320a–7b[f]). A good faith disclosure of potential fraud and cooperation with the OIG's review and resolution process are indications of a robust and effective compliance program. With self-disclosure, the provider institutes a presumption against requiring integrity agreement obligations in exchange for a release of the OIG's permissive exclusion authorities in resolving an SDP matter. The OIG states that entities that use the SDP and cooperate with the OIG deserve to pay a lower multiplier on single damages than would normally be required in resolving a government-initiated investigation. Settlements of an SDP matter are generally required at a minimum multiplier of 1.5 times the single damages.

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17 *CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 299, The Centers for Medicare & Medicaid Services, September 2004,* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r299cp.pdf, accessed on March 24, 2017.

18 *Medicare Claims Processing Manual*, The Centers for Medicare & Medicaid Services, January 2017, Chapter 30, "Financial Liability Protections," https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf, accessed on March 24, 2017.

19 *OIG's Provider Self-Disclosure Protocol, U.S. Department of Health and Human Services, Office of the Inspector General, April 2013,* https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf, accessed on March 24, 2017.

The OIG requires that a Medicare or Medicaid overpayment be reported and returned by the latter of **(1)** the date that is 60 days after the date on which the overpayment was identified, or **(2)** the date any corresponding cost report is due, if applicable.

All healthcare providers, suppliers, or other individuals or entities who are subject to the OIG's civil monetary penalty authorities, set forth in 42 C.F.R. Part 1003, are eligible to use the SDP. The OIG expects parties to disclose information with a good faith willingness to resolve all liability within the Civil Monetary Penalties Law's six-year statute of limitations as described in section 1128A(c)(1) of the Act.

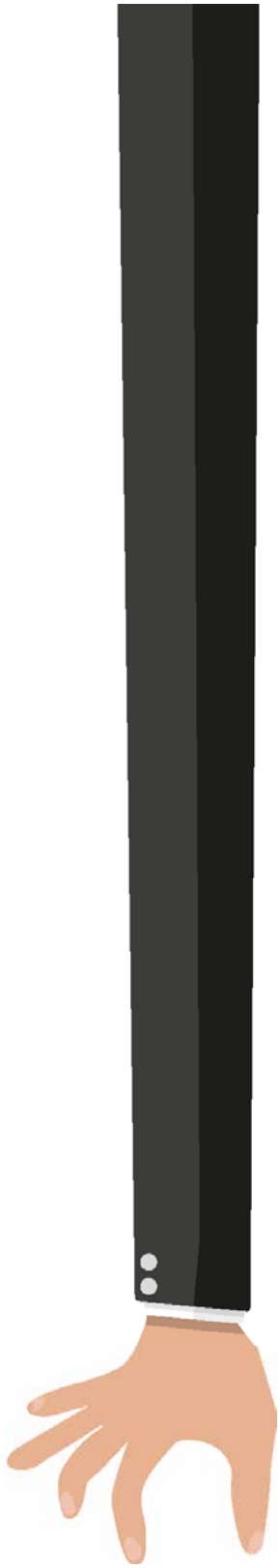
A sample determination is an estimation of damages that must consist of a review of either all of the claims affected by the disclosed matter or a statistically valid random sample of the claims that can be projected to the population of claims affected by the matter.

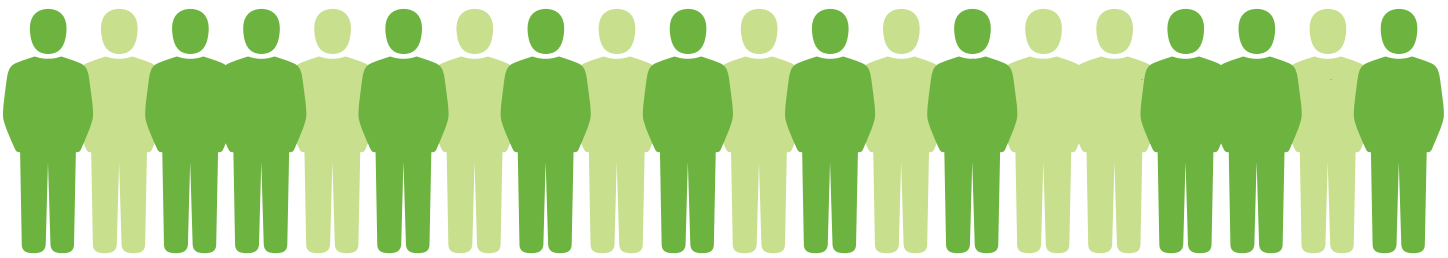
When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items and use the mean point estimate to calculate damages. If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate.

To avoid an unreasonably large sample size, the disclosing party may select an appropriate sample size to estimate damages if the sample size is at least 100 items. Generally, smaller sample sizes (closer to 100) will suffice where the population has a high level of homogeneity, and larger sample sizes will be necessary where the population contains a more diverse mixture of claim types.

Once the review is complete, and it has been determined that the error rate is more than 5% of the new overpayment identified in the sample, the net overpayment should be calculated by subtracting all underpayments from the gross overpayments identified in the sample. The error rate is calculated by dividing the net overpayment by the total dollar amount associated with the paid claim in the sample.

Extrapolation is a sampling methodology which uses a mathematical formula to take the audit results from a random sample of Medicare or Medicaid paid claims and projects those results over a much larger universe of claims. This methodology is utilized to estimate the amount due to CMS for overpaid claims.





Summary

While the topics discussed herein are broad and cover different areas of services, medical necessity is the one requirement that connects them. As we have discussed, it is rare for the regulations to be specific in this regard.

To stay compliant, providers should:

- ✓ Identify areas of concern and the rules and regulations governing the service.
- ✓ Develop training for physicians, staff, and others who are involved in providing and billing for the service(s).
- ✓ Monitor for changes to the regulations and update policies and staff.
- ✓ Develop a monitoring program that identifies areas for educational opportunities.
- ✓ If a problem is revealed, consider the use of a third-party reviewer to work through the steps for any real and potentially extensive problems that may require further action.

PYA has experience with multiple external review organizations, such as the OIG, RACs, U.S. District Attorneys, MACs, Zone Program Integrity Contractors, and other third-party payers. We offer services that include medical necessity analysis; RAC audit and appeals assistance; patient status evaluation and observation; NCDs, LCDs, and CoP documentation compliance; clinical trial protocols; Universal Bill and remittance advice; medical necessity for cardiac procedures; and Hospital Readmission Reduction Program assistance. PYA can assist your organization meet the challenges that medical necessity presents in the areas of billing, reimbursement, and compliance. To discuss how we can be of service to your organization, contact one of the following:

Denise Hall
Principal
dhall@pyapc.com
(800) 270-9629

Martin D. Brown
President
mbrown@pyapc.com
(800) 270-9629

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