



Quality Improvement Guide to Clinical Record Keeping

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Clinical Record Quality Improvement Program

Welcome to the Heraya Health (Heraya) Clinical Record Quality Improvement Program. The information in this Quality Improvement Guide is intended to help you and your office maintain member records that meet and exceed professional standards established by peers in your profession and by state and national regulatory agencies such as licensing boards and the National Committee for Quality Assurance.

These recommendations and practice tips reflect “best practices” in clinical record keeping in the peer community. They also address the specific opportunities for improvement that have been identified in your chart sample that was submitted for review.

Questions?

We hope this information is useful to you. If you have any questions, please feel free to contact one of our Heraya Medical Directors below:

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Provider Operations Manual Excerpt: Heraya Clinical Record Quality Standards

2.00 Heraya Clinical Record Quality Standards

High quality clinical care is reflected in high quality clinical documentation. Heraya is committed to assisting providers to achieve the highest levels of competency with respect to clinical record keeping. These standards establish Heraya's performance expectations for record keeping and processes to improve record keeping competency. In compliance with the National Committee on Quality Assurance, Heraya requires all network providers to ensure that a contemporaneous clinical record is established and maintained for each member who receives services from a Heraya provider. Clinical records must be maintained in accordance with all applicable professional standards and the Heraya standards outlined in this section. These best practices facilitate record keeping to ensure clinical documentation is current, detailed, and organized to promote communication, maintain member confidentiality, deliver effective member care, permit quality improvement and document medical necessity.

Definitions

Clinical Records:

The term "clinical record" means a record created by or on behalf of a provider of health care for services provided to a member. This record includes information that the member may provide concerning personal identification, demographics, social history, symptoms, and medical history. Information entered into the medical record by the provider includes the history reported by the member, the results of examinations, reports of tests and consultations, diagnoses, clinical assessments, treatment plans and treatments rendered including modalities, instructions, advice and recommended follow-up.

Protected Health Information (PHI):

Under HIPAA, protected health information is considered to be individually identifiable information relating to the past, present, or future health status of an individual that is created, collected, transmitted, or maintained by a HIPAA-covered entity in relation to the provision of healthcare, payment for healthcare services, or use in healthcare operations.

Health information such as diagnosis, treatment information, medical test results, and prescription information are considered protected health information under HIPAA, as are national identification numbers and demographic information such as birth dates, gender, ethnicity, and contact and emergency contact information. PHI relates to physical records, while ePHI is any PHI that is created, stored, transmitted, or received electronically.

PHI is only considered PHI when an individual could be identified from the information. If all identifiers are stripped from health data, it ceases to be protected health information and the HIPAA Privacy Rule's restrictions on uses and disclosures no longer apply.

Examples of where PHI may be documented include completed health care claim forms, detailed claim reports, explanations of benefits (EOB), and notes documenting discussions with members.

Occasionally Heraya requires you to submit clinical records for various purposes. When responding to these requests, it is imperative that you are compliant with Federal rules that protect member confidentiality. **Note: These rules do not apply to clinical records submitted to support billing, for Treatment Extension Requests, appeals, and other aspects of payment.**

The following are the 18 identifiers that create the definition of "individually identifiable" and can be used to identify a specific individual.

1. Names of members, spouses, relatives.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes?, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census (a) the geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (b) the initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Day and month elements of dates directly related to an individual, such as birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of "age 90 or older." **Note: this does not apply to dates of service in chart notes.**
4. Telephone numbers.
5. Fax numbers.
6. Email addresses.
7. Social Security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web Universal Resource Locators (URLs).
15. Internet Protocol (IP) addresses.
16. Biometric identifiers, including finger and voice prints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code.

2.01 Heraya Clinical Record Criteria

Confidentiality of Clinical Records

PHI is legally protected and must be handled in a confidential manner. Unless otherwise required by law, including those laws that apply to minors, disclosure of member-specific health information can be only to:

1. The individual to whom the information relates.
2. Heraya and/or a health plan contracted with Heraya to perform health care delivery, payment, administration and/or management functions on their behalf.
3. A third party only if specific authorization is obtained from the individual to whom the information relates.

Heraya providers will make member's (and members' minor children's eligible dependents) member-specific health information available to the member for inspection and copying, except as otherwise provided by law.

Clinical Record Keeping System and Standards for Availability

1. Clinical records must be organized and stored in a manner that allows easy retrieval.
2. Clinical records must be stored in a secure manner that allows access by authorized personnel only.
3. Each member will have a centralized clinical record containing all clinical records for that member. Records are organized in date-order.
4. This record will be opened at the time of a member's first visit. Entries into the record will be contemporaneous with the encounter.
5. The provider will store, retain, and maintain such records for a period consistent with applicable state and federal law.
6. The obligations of the provider regarding clinical records will survive the termination of Heraya's Professional Services Agreement, regardless of the cause giving rise to such termination.
7. There is evidence of continuity and coordination of care. Records from other providers and outside consultants will be maintained in the member's record.
8. Consultation, laboratory, and diagnostic imaging reports filed in the records will be initialed by the provider to signify review.
9. Abnormal lab and imaging results will have an explicit notation in the record of follow-up plans for notifying the member as well as the clinical intervention.
10. Records will be maintained in ink or appropriate Electronic Health Record (EHR) system.

Clinical Records Documentation Standards: "Best Practices" in Record Keeping

1. Legibility
 - a. The record is legible to someone other than the writer.
 - b. Type written is preferred.
 - c. Abbreviations used are standard and comprehensible by a peer or are accompanied by a key that explains their meaning.
2. Identification

- a. The record contains identifying personal biographic and demographic data of the member including address, home and work telephone number, marital status, employer, and alternate/emergency contact person.
- b. Each side of each page of the record contains the member's name and date of birth (or unique identifier), the provider's name and clinic of origin by name, physical address, and telephone number.
- c. Each entry is dated by month, day, and year.
- d. The author of each entry is identified by name. Services that are provided or ordered must be authenticated for each entry by the provider of or ordering provider using a valid signature. Signatures are handwritten, electronic, or stamped (only permitted where author has physical disability who can provide proof of an inability to sign due to a disability).
 - **Handwritten Clinical Record:** For a signature to be valid it must be legible. Alternatives include an illegible signature or initials next to a typed/printed legible identification of the author; illegible signature where the letterhead, addressograph or other information on the page indicates the identity of the signatory; where multiple providers are listed the author of record is specifically identified; illegible signature or initials accompanied by a signature log or attestation statement.
 - **Electronic Clinical Record:** For a signature to be valid, systems and software products must include protections against modification (e.g., time and date stamp), and administrative safeguards should be applied that correspond to standards and laws, e.g., using signature and secure login functions appropriately. Best practice would include the following elements:
 - Full printed name of the author at the end of the entry.
 - Date.
 - Time.
 - Digitized signature or signature statement, e.g., electronically signed by, signed by, authenticated by, reviewed by, etc.

3. Clinical Information

- a. The complaint prompting the member to seek care is noted. The mode of onset, location, nature, duration, aggravating/palliating factors (OPQRST) are documented.
- b. Prior interventions and outcomes of previous treatment of the presenting condition are indicated.
- c. Other pertinent current medical history, system review, past medical history, family, and socioeconomic history are noted.
- d. Notations of all significant illness, surgery, and injury. For children and adolescents, pre-natal care, birth, operations, and childhood illness are documented.
- e. Clinical indications for laboratory and diagnostic imaging studies are documented.

4. Member Safety

- a. Current and significant past medication (including Rx, OTC, and natural medicines) use is documented.
- b. Allergies, medication allergies, intolerances, adverse reactions, and contraindications to potential treatments are clearly noted.

c. Informed consent is obtained and properly documented and included in the clinical record. This process includes a verbal discussion to include the following elements often referred to as the “PARQ” conference:

- (P) explanation of proposed examination, procedure, or treatment in general terms,
- (A) viable alternatives,
- (R) material risks,
- (Q) ask if the member has any questions.

This can be documented in the clinical record as PARQ. If the member requests further information or has specific questions the provider can underline PARQ and should note the question and the more detailed information provided. It is also recommended that the member sign a document acknowledging they have been part of the informed consent process, that the material risks have been disclosed, including a description of those risks, and that the member has agreed to the procedures, understands the risks, understands the alternatives, and the opportunity to ask questions has been provided. This could be accomplished using a prepared written consent form or other format that must be signed by the member and should be signed by the provider. It is important that providers have a discussion directly with the member and not rely exclusively on these forms.

5. Preventive Health Care

- a. There is documentation and advice when appropriate for routine preventive health measures, such as:
 - Tobacco use.
 - Alcohol use.
 - Exercise habits.
 - Diet.
 - Screening for obesity.
 - Hypertension.
 - Cholesterol.
 - Sleep habits.
 - Known allergies.
 - Mammography.
 - PAP.
 - Stress.
 - Assessment of behavioral health status.
- b. Inquiry about and referral for significant chronic conditions (CAD, heart failure, diabetes, asthma) is noted.

6. Integrated Care

- a. Member's other health care providers (PCP, specialists, IH) are identified.
- b. Permission to contact member's other care providers is documented.
- c. Contact with other care providers (written, telephone, etc.) is documented.

7. Evaluation

- a. Vital signs are recorded.
- b. Findings of abnormal and pertinent negative physical and laboratory examinations and diagnostic imaging are documented. The examinations are appropriate for the

presenting condition. The test results are clearly documented in the record by being adequately described and results properly qualified and quantified.

- c. Appropriate outcomes assessments are used, such as functional [ADL] assessment, physiologic measurements, and outcome assessment tools [VAS, pain drawing, etc.].

8. Assessment

- a. The provider's initial assessment of the member's condition, whether a working diagnosis, clinical assessment or impression is clearly indicated. Progress of the member's condition is noted in every chart note.
- b. The initial and ongoing assessments are consistent with the history, complaints, and examination findings.

9. Treatment Plan

- a. The treatment plan is documented.
- b. Expected visit frequency, duration and interventions are noted.
- c. Goals/expected outcomes of treatment are identified.
- d. Obstacles to recovery and strategies to overcome them are documented.

10. Follow-up Visits

- a. Each entry in the clinical record is visit specific where all components of a routine visit with an established member are documented.
- b. Review of chief complaint, effect of the prior treatments, changes since the last visit and pertinent interim history are documented.
- c. Relevant examination findings are noted.
- d. Current clinical assessment of the member's condition and the member's progress are noted.
- e. The treatment rendered, recommendations and instructions to the member at the visits are documented.
- f. Follow-up is documented.

11. The patient record should never be backdated, erased, deleted, or altered in any way. If corrections need to be made or addendums added to a written record, a line should be drawn through the correction, or the addendum inserted and the change initialed and dated. In the case of electronic patient records, corrections or amendments should be made using an addendum that is signed or initialed and dated. In both cases, the original record should be preserved.

2.02 Performance Goals for Clinical Record Quality Improvement and the Clinical Record Quality Improvement Program (CRQIP)

Performance Goals

Assessing the Quality of Clinical Records

Clinical record keeping quality is measured by discipline-specific scoring tools that were developed by provider focus groups. A minimum quality threshold has been established for each discipline and noted on the applicable scoring tool.

Initial Applicants

Initial applicants are required to submit clinical records at the time of application for initial credentialing and are required to meet the minimum quality threshold prior to acceptance on the network. Initial applicants are notified of this requirement and provided a copy of the scoring tool in the credentialing application for awareness of the scored elements.

CHP Contracted Providers

For contracted providers, clinical records are routinely monitored for quality improvement purposes, in concert with record reviews related to claims submissions and Heraya's Utilization Management Program. Heraya contracted providers who do not meet threshold will be allowed to enroll and participate in the CRQIP twice. Failure to pass CRQIP or maintain clinical record quality standards may result in Heraya offering the contracted provider the opportunity to resign. Otherwise, Heraya will terminate their participation for breach of contract in accordance with the Professional Services Agreement.

All Heraya contracted providers who meet threshold are assigned to one of three categories below and are notified in writing of their status.

1. ***Audit Pool:*** This pool is comprised of 1) contracted providers who have met or exceeded the scoring tool threshold specific to their discipline and 2) initial applicants who are automatically placed in this pool since only one clinical record review has occurred. The providers in this pool will be required to submit clinical records periodically at Heraya's request.
2. ***Exempt Status:*** Heraya providers who have consistently demonstrated the ability to keep quality clinical records by scoring at least 85% twice consecutively, without being enrolled in CRQIP, may be exempted from further clinical record quality reviews. This status requires approval by a clinician reviewer or a Heraya Medical Director. All exempt providers may be subject to periodic random clinical record quality reviews if deemed necessary by a Heraya Medical Director.
3. ***Exception Status:*** Exceptions to meeting the minimum quality threshold may be granted by the Heraya Chief Clinical Officer. Criteria for determining an exception include:
 - a. Number of current active members.
 - b. Geographical location.
 - c. Number of other providers in the geographic area meeting threshold standards.
 - d. Tenure on network.
 - e. Business needs.

Change of Status

A clinician reviewer or a Heraya Medical Director has the right to change a provider's status. This change will be communicated to the provider by letter. Medical necessity reviews performed by Heraya or its contracted health plans or related activities which indicate non-compliance with maintaining threshold standards will result in auditing of the providers' clinical records. This policy will apply to all contracted providers, including those who may have been previously exempt from clinical record audits.

Initial applicants and Heraya contracted providers whose clinical records do not meet the established minimum thresholds are enrolled in and must successfully complete the CRQIP which is described below.

CRQIP Process

Clinical records not meeting the established thresholds will result in provider enrollment in the CRQIP. The following process applies to both initial applicants and contracted providers:

1. Heraya notifies the provider in writing of the CRQIP enrollment. This notification will contain the following:
 - a. Instructions on when and how to submit a new set of clinical records. All enrollees are provided 60 days to finish the program from the initial date of notification.
 - b. A copy of completed scoring tool and notes scored.
 - c. Quality Improvement Guide to Clinical Record Keeping containing information relating to areas where the applicant scored low.
 - d. A copy of the blank applicable scoring tool and guidelines.
2. Clinical records are submitted to Heraya by the provider within 45 days of enrollment.
3. Clinician reviewers audit clinical record quality utilizing scoring tools based on the discipline specific performance criteria.
4. Heraya notifies the provider in writing of scored results. The course of action for those providers whose scores pass threshold and for those who do not is outlined below.
5. Heraya scans all relevant CRQIP information to the provider database.

Scores At or Above Threshold

Initial Applicants: Clinical records meeting the minimum quality threshold for initial applicants will result in the continuation of the credentialing process. The provider is notified of the passing score, provided a copy of the scoring tool, notified of placement in the Audit Pool for future periodic clinical record reviews and that the credentialing process will be completed.

Contracted Providers: Clinical records meeting the minimum quality threshold for contracted providers will result in notification of the passing score. The provider will be given a copy of the scoring tool and, if applicable, notified of a status change.

Scores Below Threshold

Initial applicants or contracted providers whose clinical records do not meet the minimum quality threshold after the CRQIP review will be given the following two options:

1. The provider will be given the opportunity to work with a mentor to meet Heraya's minimum threshold requirements.
2. If the provider should choose not to work with a mentor, Heraya may proceed to terminate their participation for breach of contract in accordance with the Professional Services Agreement or for initial applicants, may proceed with application closure.

Clinical Record Mentors

If the initial applicant or contracted provider chooses the option to work with a mentor to meet Heraya's minimum quality threshold, the provider will be contacted by the assigned mentor and repeat the CRQIP process described above.

2.03 Clinical Record Quality Improvement: Visit Specific Clinical Records Program

Clinical records not meeting the visit specific requirement will result in provider enrollment in the Clinical Record Quality Improvement: Visit Specific Clinical Records Program.

Performance Goals for Clinical Record Quality Improvement: Visit Specific Clinical Records Program

Assessing the Quality of Clinical Records

Requirements have been established for all Heraya providers to document visit specific entries in the clinical record. This is noted on the applicable scoring tool and scoring guidelines.

Initial Applicants

Initial applicants are required to submit clinical records at the time of application for initial credentialing and are required to meet the visit specific requirement in their clinical record keeping. Initial applicants are notified of this requirement and provided a copy of the scoring tool and scoring guidelines in the credentialing application for awareness of the scored elements.

Heraya Contracted Providers

For contracted providers, clinical records are routinely monitored for quality improvement purposes, in concert with record reviews related to claims submissions and Heraya's Utilization Management Program.

Initial applicants and Heraya contracted providers whose clinical records do not meet the visit specific requirement are enrolled in and must successfully complete the Visit Specific Clinical Records Program which is described below.

Visit Specific Clinical Records Program Process

The following process applies to both initial applicants and Heraya contracted providers:

1. Heraya notifies the provider in writing of their enrollment in the Visit Specific Clinical Records Program. This notification will contain the following:
 - a. A memo detailing the visit specific requirements and instructions on the next step. All enrollees are provided six (6) months to finish the program from the initial date of notification.
 - b. A copy of the completed scoring tool and notes scored.
 - c. A copy of Best Practices in Clinical Record Keeping: Visit Specific Chart/Progress/Encounter Notes.

2. A follow up memo is sent six (6) months from the initial date of notification to request a new set of clinical records.
3. Clinical records are submitted to Heraya by the provider.
4. The Regional Medical Director or clinical reviewer of the same discipline will audit clinical record quality on the explicit discipline specific performance criteria.
5. Heraya notifies the provider in writing of the results. The course of action for those providers who meet the visit specific requirement and for those who do not is outlined below.
6. Heraya scans all relevant information to the provider database.

Providers meeting the requirements

Clinical records meeting the visit specific requirements will result in notification of successful completion of the program.

Providers not meeting the requirements

Clinical records that do not meet the visit specific requirements will be given the following two options:

1. The provider will be given the opportunity to work with a mentor to meet Heraya's requirements for visit specificity.
2. If the provider should choose not to work with a mentor, Heraya may proceed to terminate their participation for breach of contract in accordance with the Professional Services Agreement or for initial applicants, may proceed with application closure.

Best Practices in Clinical Record Keeping: The Basics

Introduction

Since its inception many years ago, Heraya Health (Heraya) has engaged panel providers in developing “Best Practices” in clinical record keeping. Clinician advisors from each discipline have contributed their expertise and experience to information gleaned from authoritative sources to develop record keeping policies, procedures and resources to guide and assist Heraya providers. High-quality clinical records support high quality member care.

Why Keep Clinical Records?

The art and science of clinical record keeping deserves, but often does not get, as much attention as the art and science of delivering quality health care to members. The dictum that “if it didn’t get written down, it didn’t occur” is one that all health care providers must respect. Heraya is committed to assuring that providers maintain excellent clinical records. There are many reasons why documenting member care is a critical function in any health care setting.

- **Professional and Legal Standards**

Health care records are both clinical and legal documents. Professional and legal standards routinely include requirements and recommendations about record keeping. Failure to document member care adequately can be considered evidence of negligence. For example, some statutory practice acts specify the need for complete and accurate clinical records. In Washington State WAC 246-808-560, Documentation of care, states, “The recordkeeping procedures of a chiropractor shall be adequate to provide documentation of the necessity and rationale for examination, diagnostic/analytical procedures, and chiropractic services.” Oregon Administrative Rules Chapter 811-015-0005, Records, specifies that, “It will be considered unprofessional conduct not to keep complete and accurate records on all members.”

- **Quality Member Care**

If compliance with the state licensing board was not reason enough to maintain good records, providing excellent member care should motivate any practitioner to have excellent clinical records. Good chart notes support good member care in several ways:

- Memory is not infallible. In a busy practice with diverse member populations, keeping track of each member’s unique clinical presentation, treatment plan, progress, precautions and outcomes would be impossible without a systematic and organized written record.
- Clinical decision-making hinges on good documentation. Decisions about how best to help a member and what works and what doesn’t as treatment proceeds is dependent on a comprehensive record of the member’s condition (symptoms, signs, examination and lab findings, etc), what was done, and how the member responded to the care.

- Continuity of care is enhanced by good clinical records. Whether a member's care is shared among different providers in one facility or is transferred from one office to another, sharing legible, understandable and accurate clinical information with other providers reduces unnecessary testing, saves time, and helps members get the care they need.
- Member safety can be maximized with consistent documentation and prominent display of warnings and contraindications to treatment.

- **Malpractice Risk Management**

The importance of excellent clinical records is perhaps never appreciated so much as in malpractice actions. While we all strive to produce the best outcomes for our members, untoward events do occur, and members do sue their health care providers alleging malpractice. In those unfortunate instances complete, thorough and accurate clinical records often make the difference between a successful defense and an unfavorable outcome for both the member and the provider.

- **Documenting Medical Necessity**

Heraya has an obligation to payers to provide care that is medically necessary. Generally speaking, medically necessary care is that care, which is appropriate for the condition, is being provided for that condition, is within the standards of good care, and is for the benefit of the member, not the caregiver. Quality clinical documentation can demonstrate all of these elements and assure compliance with requirements of payers including private insurance, workers' compensation, personal injury and Medicare.

Best Practices in Clinical Record Keeping: Identification

One of the most basic elements of a clinical record is full and complete identification on each page of the chart, whether it is an intake form, a member health history, examination form, daily chart or treatment notes. The provider should be identified by name, professional designation, name of clinic of origin with physical address and phone number. The member should be identified with a full name and date of birth or a unique identification number. The member, the clinic, the author and their verifying signature for each entry must be clearly indicated. This “best practice” in record keeping is endorsed by many health care organizations, regulatory agencies – such as the National Commission on Quality Assurance (NCQA) – and by state authorities.

Note: If forms are two-sided, each side should have complete identification.

Some providers complain, “Why the over-kill? I know who my members are.” True, while the chart is in your office and under your control, everything is clear. However, when copies are made for another health care provider, an insurance company or an attorney (a completely identified record with a full signature or validated electronic signature is an unassailable legal record), and your identification and the member’s identification is not on every page of the paper record, the receiver may not be able to tell for certain that that page of the record is from you or pertains to your member. Also, accidents happen, and if your records are vandalized, misplaced or fall to the floor, proper identification of each page will allow successful reassembling of the files.

Every page (front/back) should include the member name and DOB or unique identification number, and make sure that your name, professional designation, name of clinic of origin with address and phone number is printed on every page. In multiple practitioner offices, identify the practitioner who is seeing that member.

Chart

- Each entry into the chart should be identified by day, month, year, the author of the note and include a verifying signature.
- Practitioners with multiple licenses shall indicate on each member record under which license their service was rendered.

Best Practices in Clinical Record Keeping: Documenting Informed Consent

Introduction

Documentation of informed consent in the member's chart is important from a number of perspectives: health care ethics, malpractices risk management, and effective member management. The most important goal of informed consent is that the member has an opportunity to be an informed participant in their health care decision making. It is generally accepted that complete informed consent should be obtained from members before carrying out any diagnostic or therapeutic procedure and includes a discussion of the following elements:

- The nature of the treatment plan, procedure or diagnostic testing
- Reasonable alternatives to the proposed intervention
- The relevant risks, benefits, and uncertainties related to each alternative, including the risk of refusing care
- Assessment of member understanding
- The acceptance of the intervention by the member

Ethics

Informed consent is the process by which fully informed members can participate in choices about their health care. It originates from the legal and ethical right each member has to direct what happens to their body and from the ethical duty of the physician to involve the member in his or her health care. Fully informed members have adequate foreknowledge and understanding of the recommended treatment and/or diagnostic testing, the anticipated outcomes, and alternatives to it. It is the process of effectively communicating with members in terms they understand and then allowing them the opportunity to ask questions.

Malpractice Risk Management

Despite our best efforts as careful clinicians to do what is right, bad outcomes do happen. In an informed consent process, the potential risks of an adverse outcome are dealt with up front with each member in a straight-forward and non-threatening manner. Having this conversation with a member first helps a great deal in those few cases with a less-than-optimum outcome. Members who have access to open information exchanges are less likely to claim malpractice.

To protect your patient and yourself in case of malpractice, in addition to carrying adequate liability insurance it is important that communication about the informed consent process itself be documented in the clinical file. Good documentation can serve as evidence in a court of the law that the process indeed took place. A timely and thorough documentation in the member's

chart by the provider of the treatment can be a strong piece of evidence that the provider engaged the member in an appropriate discussion.

Of the complaints that we receive at Heraya, the most common is “the practitioner hurt me.” Often the member goes on to describe an uncomfortable procedure (adjusting, massage, acupuncture needles) followed by post-treatment soreness, stiffness or other symptoms. A complete “informed consent” discussion with that member acknowledging the risk of discomfort with the procedure and the potential of post-treatment soreness may well have prevented this perception and prevented a complaint.

Member Management

Informed members make better health care decisions. Open discussion with members about treatment plans, common alternative treatments that may be available, the risks that may be associated with treatment, including refusing care, and invitation to members to ask questions and receive clarification are primary activities for all health care providers. Often dubbed the “PARQ” conference (an acronym for “procedures, alternatives, risks, and questions”), this open communication empowers each member to obtain all necessary information, ask questions and to collaborate with the clinician in making decisions about care.

Members who are able to make informed decisions are more likely to follow through on your treatment recommendations. They have demonstrably better clinical outcomes, are more satisfied with you and your care and they are more likely to refer their family and friends.

Documenting Informed Consent: “PARQ”

Informed consent is a process involving verbal discussion as well as proper documentation. Heraya recommends as a “best practice” that informed consent be fully documented and included in the clinical file.

One common option for documenting informed consent is noting the acronym “PARQ” which can be written in the member’s chart indicating that the provider has explained the procedures (P), viable alternatives (A), material risks (R), if any, and has asked if the member has any questions (Q). “PARQ” should be noted prior to the implementation of any treatment. If the member requests further information or has specific questions, the provider can underline the PARQ chart notation to reflect the member’s request. The provider should note the particular question and note the more detailed information provided. While this is an appropriate method of documenting that this process has occurred, there is no substitute for the member’s written confirmation of those facts.

It is also recommended that the member execute some document acknowledging that they have been part of an informed consent process, the material risks have been disclosed including a description of those risks and that the member has agreed (“consented”) to the procedures understanding any risks inherent to that procedure. This could be accomplished

using a prepared written consent form that must be signed by the member and should be signed by the doctor. Again, it is important to note that practitioners should not rely exclusively on those forms and must communicate directly with the members.

As new conditions occur that may require different evaluation procedures or different treatment procedures, additional informed consent should be obtained from the member. In addition, consent given to one physician is not consent for any other physician unless the member agrees to the substitute. This assent to the substitute physician should be noted in the clinical record.

THE MINOR MEMBER

As with all members, informed consent is required for minor members. There are different considerations required based on the type of provider delivering the service as well as the services that are being provided. For the purposes of Best Practices, it is recommended that the provider review the specific statutes or rules regarding obtaining informed consent from a parent/legal guardian or the minor members, whichever is appropriate, that applies to the services rendered in the state in which they practice.

Best Practices in Clinical Record Keeping: SOAP Notes

Introduction

In 1968, Lawrence Weed, MD, developed the problem-oriented medical record (POMR) "... to develop a more organized approach to the medical record..."* Although only a component of the POMR, the SOAP format has become the standard in clinical record keeping for daily chart notes in ambulatory settings.

Proper record keeping using the SOAP method improves member care and enhances communication between the provider and other parties: claims personnel, peer reviewers, case managers, attorneys, and other physicians or providers who may be involved in the care of your members.

Heraya does not require, but strongly encourages the use of the SOAP format. If SOAP itself is not used, the elements embodied in SOAP must be recorded.

The Basics

Chart notes must be legible, in legible handwriting or, preferably, typed. The provider's identification (name, address and phone) and member's name and unique identifier such as date of birth (DOB) or record number must be indicated on each side of every page. Every chart entry must be dated and signed by the person entering the note (this includes office personnel who make entries in the chart). Standard abbreviations are acceptable as long as they are easily understandable and interpretable by others (see articles on the Heraya website).

There are many styles of chart notes that can describe the critical elements of a properly documented member encounter, however narrative notes in SOAP format are the standard. Check-box formats, pre-printed forms, travel cards, computer-generated notes, bar code SOAP notes, and other automated systems can improve efficiency, but they can also produce notes that are clearly "canned," containing little clinical content and unfortunately substitutes for proper documentation of the clinical thought process.

Effective chart notes must reflect the four criteria required to document medical necessity.

1. The member's chart must reflect subjective complaints that are consistent with a lesion, injury, or condition.

* Weed L. Medical records that guide and teach. NEJM Vol. 278, No. 11 & 12. 1968.

2. The examination must confirm the existence of a lesion, injury, or condition that is consistent with the member's complaints and the exam findings must be documented in the chart.
3. The management of the case or treatment rendered must be considered appropriate for the condition.
4. The member chart should reflect overall improvement with time both subjectively and by clinical examination findings.

The Anatomy of "SOAP"

S = *Subjective or symptoms and reflects the history and interval history of the condition.* The member's presenting complaints should be described in some detail in the notes of each office visit. Using the member's own words is best. Routine use of one-word entries or short phrases such as "better", "same", "worse", "headache", "back pain" is not sufficient. In follow-up notes, "S" is an update of the chief complaints elicited during the initial evaluation of the member. The complaints should reflect change over time, e.g. duration, intensity and frequency of pain as well as responses to the previous treatment, resumption of daily or occupational activities, intervening injuries, and exacerbations. "S" should also describe any changes in the member's activities and physical capacities in the interim between treatments. Also included in this section are explanations for any hiatus in treatment and the member's compliance with recommended home care instructions.

The requirement of the treating physician to measure and record clinically meaningful functional capacity improvement has led to the development and use of O.A.T.S., an acronym for (O) Outcome (A) Assessment (T) Tools. This would include items like the Neck Disability Index, Oswestry, DASH, Pain Disability Questionnaire, etc. and should be recorded in this section also.

O = *Objective or observations.* This section includes inspection (e.g., "member still walks with antalgic gait") as well as more formalized reevaluations such as ranges of motion, provocative tests, and specialized tests. The extent of the reevaluation at each office visit is determined by the information gathered in "S" together with the original positive clinical findings as well as changes in "O" from previous office visits. Findings should be qualified and quantified in order to be able to ascertain progress/response to care over time. Indicators for treatment should always be included in order to document necessity of the treatment provided and described in the "Plan" section of the note, for example motion palpation findings, stagnation of blood and chi, or abnormal lab values.

A = *Assessment.* Initially this is the diagnostic impression or working diagnosis and is based on the "S" and "O" components of SOAP. On follow-up visits the "A" should reflect changes in "S" and "O" as a response to time, treatment, and other interim events (e.g., "Cervical strain, resolving" or "exacerbation of right sacroiliac pain"). "A" should be continually updated to be an accurate portrayal of the member's present condition. Other components of "A" may include

the following where appropriate: member risk factors or other health concerns; review of medications, laboratory or procedure results, and outside consultation reports.

P = Plan or Procedure. The initial plan for treatment should be stated in “P” section of the member’s first visit. A complete treatment plan includes treatment frequency, duration, procedures, expected outcomes and goals of treatment. An initial treatment plan may be for an initial trial of treatment over a short interval with a re-assessment and further treatment planning at that later time.

On each follow-up visit, “P” should indicate specific areas of treatment, e.g. C5 right rotation fixation/hypomobility, modalities (including specifics of type, duration/stop-start times, intensity) any procedures performed that day, and continuation or changes in the overall treatment plan. “P” should also describe what the member is to do between office visits, e.g. exercises, diet/nutrition/medication, what the expected course of treatment is, what further tests or consultations/referrals might be ordered (e.g., “Obtain cervical MRI or consultation with neurologist if upper extremity paresthesia persists”), and the disposition of the case (discharge, referral, etc.). It is also appropriate to include in this section any comments with respect to the member’s compliance.

Other items or events to be charted include:

- Any phone or personal contact with the member.
- Failed appointments, rescheduled appointments, or when the member is significantly late for an appointment.
- The receipt of important correspondence regarding the case.
- Requests for medical records sent or received.
- Transmittal of records, correspondence, etc.
- X-rays and other imaging studies, lab work, consultation reports.

Amending the Clinical Record

The patient record should never be backdated, erased, deleted or altered in any way. In the case of electronic patient records, corrections or amendments should be made using an addendum that is signed or initialed and dated. If corrections need to be made or addendums added to a written record, a line should be drawn through the original entry, the correction made or the addendum inserted, and the change initialed and dated. In both cases, the original record should be preserved.

Best Practices in Clinical Record Keeping: Visit Specific Chart/Progress/Encounter Notes

Introduction

Complete and thorough documentation of each clinical encounter using visit specific entries is essential to the process of providing the best quality member care. The introduction and accelerated adoption of electronic health records (EHR) systems to record information from the member encounter has created some benefits and challenges. Some of the benefits and challenges are highlighted below but the focus of this Best Practice is to ensure the adoption of this technology is successful in preserving the visit specific entry requirement.

Benefits

Some of the areas where EHR systems can improve the process of healthcare include the following:

- Minimize errors, improve member safety, and support better member outcomes.
- Improve quality of care and risk management.
- Improve public health outcomes.
- Improve documentation and coding.
- Allow for better coordination of care between providers.
- Improve member access to health record data.

Challenges

Some of the challenges for providers in implementation and using EHR systems include the following:

- Customization required for work flow.
- Learning curve for use.
- Interference with face-to-face member care.
- Increased time required to complete charting.
- Copy-paste/ whole note or visit-to-visit cloning/auto-populate/Same As Last Time (SALT), and over-documentation/ “note bloat”.

Visit Specific Notes

The documentation of visit specific notes for each member encounter is essential to the process of providing the best quality care. In the world of modern healthcare where time is at a premium, producing a quality clinical record requires attention to detail. Most EHR systems are designed to assist in this process by using templates, macros, and other automated approaches. These methods can be very helpful to a clinician; however, the evidence clearly demonstrates it still requires a significant proportion of the member encounter time to document a quality driven visit specific note. Where the provider uses the EHR to generate a

clinical record that is not visit specific using methods such as copy-pasting, whole note or visit-to-visit cloning, auto-populating, or Same As Last Time (SALT), the outcome does not meet professional standards for clinical record keeping. Some of the unintended consequences of these types of chart note entries are as follows:

- Failure to achieve the medical necessity criteria due to repetition/no documented change in subjective and objective content resulting in denial of services.
- Failure to provide an accurate or meaningful clinical picture of the member with implications on the quality and safety of member care.
- Violation of professional licensure standards/rules, state and/or federal law, e.g. Oregon Administrative Rule Chapter 811 Division Consumer Protection Records 811-015-0005 (1): "It will be considered unprofessional conduct not to keep complete and accurate records on all members, including but not limited to case histories, examinations, diagnostic and therapeutic services, treatment plan, instructions in home treatment and supplements, work status information and referral recommendations."

Another method that results in the same concerns is using software generated notes where there is no visit specificity, i.e. the same thing is repeated from visit to visit but the wording is slightly altered, as depicted in the following chart:

Patient Visit	Subjective Documentation
Day One	"She is afflicted by a moderate degree of intermittent dull pain with stiffness and soreness in both sides of her neck."
Day Two	"In her neck bilaterally, the patient is feeling a moderate degree of dull pain with stiffness and soreness which occurs intermittently."
Day Three	"She is experiencing in her neck on both sides, an intermittent dull pain with stiffness and soreness of a moderate degree."

Practical Application of Visit Specific Clinical Record Keeping

There are a number of conditions seen by healthcare providers where it may take a period of time and/or number of office visits before there are more profound changes in the member's health status. One analogy to illustrate this point is using a light switch where most conditions respond like a dimmer switch rather than a simple off-on switch. The clinical record is where it is appropriate to record the specific details of the member's condition that are relevant and representative of their status at each visit. This may include changes that are not necessarily profound in magnitude but are meaningful (e.g. same pain level but decreased frequency) and should be included at each visit. For each condition and individual member there is a continuum of response to care from no improvement to complete recovery over time. This should be represented in their visit specific clinical record. Following are some examples for each section of the SOAP note that may assist in application of these concepts.

- **Subjective:** A number of items should be considered at each visit to include in the subjective portion of the clinical record where meaningful change may be represented. This should include elements using the member's own words when possible indicating their status. Further exploration of the duration, intensity and frequency of a symptom such as pain can be qualified and quantified and documented by using an Outcome Assessment Tool (OAT) such as a pain scale, e.g. Visual Analogue, Numerical Rating Scale or Member Specific Function Scale. This could also include a frequency component ranging from constant to occasional. Additional items to consider, including in the context of member status where change in comparison to the initial visit for an episode of care, are as follows: specifics of response to care, effects on Activities of Daily Living (ADL's) such as sleep, walking, etc., palliative and provocative factors, medication dose and frequency, work status/capacity, quality of symptom, radiation if any, and timing.
 - Sample Subjective Documentation:
 - Non-visit specific subjective clinical record: copy-pasted from initial/prior/previous visit; e.g., "The member returned today reporting that they are still having pain in the neck, 2/10."
 - Visit specific subjective clinical record: "The member returned today reporting that they are still having pain in the neck, 2/10, however the pain is less constant/more intermittent. It no longer radiates to the upper shoulders and after the last visit there was almost no pain and improved neck mobility for about 24 hours. They are only taking 600mg ibuprofen twice per day whereas they were taking 800mg three times per day initially. They are performing the exercises and not having any trouble with them. Sleeping is still difficult as changing positions still wakes them up, but this is less frequent, and they are able to return to sleep without significant delay."
- **Objective:** Qualification and quantification of objective findings provide the evidence where meaningful changes may be reflected in documentation of visit specific clinical records. The objective component of the visit may not demonstrate meaningful changes at each visit depending on the condition and the member, however it's reasonable to expect changes over the course of several visits with most conditions and this should be reflected in the clinical record. This can include some of the following elements in comparison to the initial visit for an episode of care or condition based treatment: degree of antalgia; joint range of motion (ROM) with degrees and associated qualified and quantified symptoms; tenderness (e.g., 1-4/4); muscle hypertonicity (e.g., mild, mild-moderate, moderate, moderate-severe, severe); orthopedic and neurological testing (e.g., muscle testing 0-5); tongue & pulse; other examination/objective findings such as blood pressure, laboratory testing, weight, edema, etc.
 - Sample Objective Documentation:

- Non-visit specific objective clinical record: copy-pasted from initial/prior/previous visit; may include items that were performed on the initial visit but weren't performed on a subsequent visit (e.g., vitals, labs, physical exam findings such as lung or heart sounds, ROM, orthopedic tests, etc.) providing erroneous/false information.
- Visit specific objective clinical record: "examination findings are as follows: mild LLF lumbar antalgia; +2/4 tenderness paracervical areas C4-6; paracervical muscle hypertonicity mild-moderate; cervical ROM full in all planes with mild local right side neck pain in right rotation with all other planes being asymptomatic; segmental joint dysfunction C4-5 on the right."

- **Assessment (may include Action/Treatment):** The assessment should be updated in some detail at each visit. This documents the updated visit specific clinical impression/thought process based on the subjective and objective components of the clinical record to determine the member's response to care. This should be as specific and descriptive as possible and may include updating components such as the phase (e.g. acute, subacute, chronic), complicating or associated factors, concomitant diseases/co-morbidities. This section also may include action or treatment which is detailed in the Plan section below.
 - Non-visit specific clinical record assessment: copy-pasted from initial/prior/previous visit, e.g. "Diagnosis unchanged from last visit, member is improving as expected."
 - Visit specific clinical record assessment: "continued slowly improving sub-acute cervical facet syndrome/primary hypertension as evidenced by decreased pain/improved ADL's/improved ROM/decreased daily home and in clinic blood pressure readings".
- **Plan (may include Procedures/Treatment/Prognosis):** Included are updated detailed specifics of treatment (e.g. modalities and procedures, dietary recommendations, medications, member instructions, etc.), prognosis, compliance, assessment of treatment plan (consistent with diagnosis, deriving expected outcomes and goals of treatment, continue or change based on assessment), consideration and/or documentation of consultations/referrals/imaging.
 - Non-visit specific clinical record plan: copy-pasted from initial/prior/previous visit, e.g. "Adjust T4, continue with current plan, PTR Wednesday."
 - Visit specific clinical record plan: "Treatment included manual manipulation at T4 on the right performed supine with good release and improved segmental mobility; continue with gluten free diet/spinal stabilization exercises with good member compliance. The member is making good progress with this being the 4th/6 planned visits. They

should return 1x/week X 2 weeks with plans to add levator and trapezius stretching/omega-3 dietary changes at their next visit."

Summary

The clinical record should document a clear picture of the member's condition and their response to care in a visit specific manner. As outlined in this best practice document, there are challenges as well as benefits associated with the technology that incorporates the EHR into the member encounter. There is a learning process that accompanies this process and one of the keys to successful implementation is understanding that documentation of clinically meaningful information at each visit is an essential component in providing the highest quality member care.

Best Practices in Clinical Record Keeping: Clinical Assessment of Pain Intensity

Pain is an individually experienced phenomenon producing widely different sensory effects that cannot be measured by objective physical examination. The importance of clinical pain assessment of pain however has led to the development of a number of validated clinical tools designed to measure the self-expression of a member's pain level. These self-reporting tools are the gold standard of pain assessment and can be used to evaluate the severity of the pain, its effect on physical functions and the effect of treatment when measured over time.

The experience of pain is a complex of psychophysiological processes. Current neurophysiological research is beginning to truly “objectify” the pain experience. Through experimental quantification from diagnostic imaging and electroencephalography, objective measures of pain are increasingly available, but relevant primarily in a research setting. Pain assessment in clinical practice however must rely on the lower tech approach of self-reporting. These “semi-objective” measures can be useful in care planning and outcomes assessment.

Among the most commonly used and well known are the Visual Analog Scale (VAS) and Numeric Pain Scale (NPS). The VAS uses an unmarked horizontal line of precisely 100mm on which the member marks their pain level ranging from no pain to most pain (Figure 1).

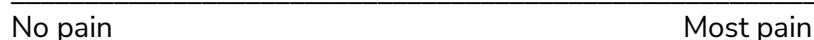


Figure 1. Visual Analog Scale (VAS) for pain severity measurement.

The NPS uses a horizontal line with a segmented scale of numbers marked from 0-10 where the member is asked to place their mark rating their pain (Figure 2). The length of the line is not essential for this scale.



Figure 2. Numeric Pain Scale (NPS).

These tools can be expanded to include multiple measures of pain, e.g. Quadruple VAS (QVAS) where pain is rated 1) present 2) average or typical 3) at worst 4) at best.

Another pain measuring tool that is often combined with a numeric pain scale and physical or functional capacity is the pictographic or Faces Pain Scale (FPS). This employs pictures of faces expressing levels of pain from no pain to most pain and was originally developed to assess the intensity of children's pain. Heraya Health has developed a vertical pictographic FPS with an associated numeric pain level, verbal description of pain, physical capacity and

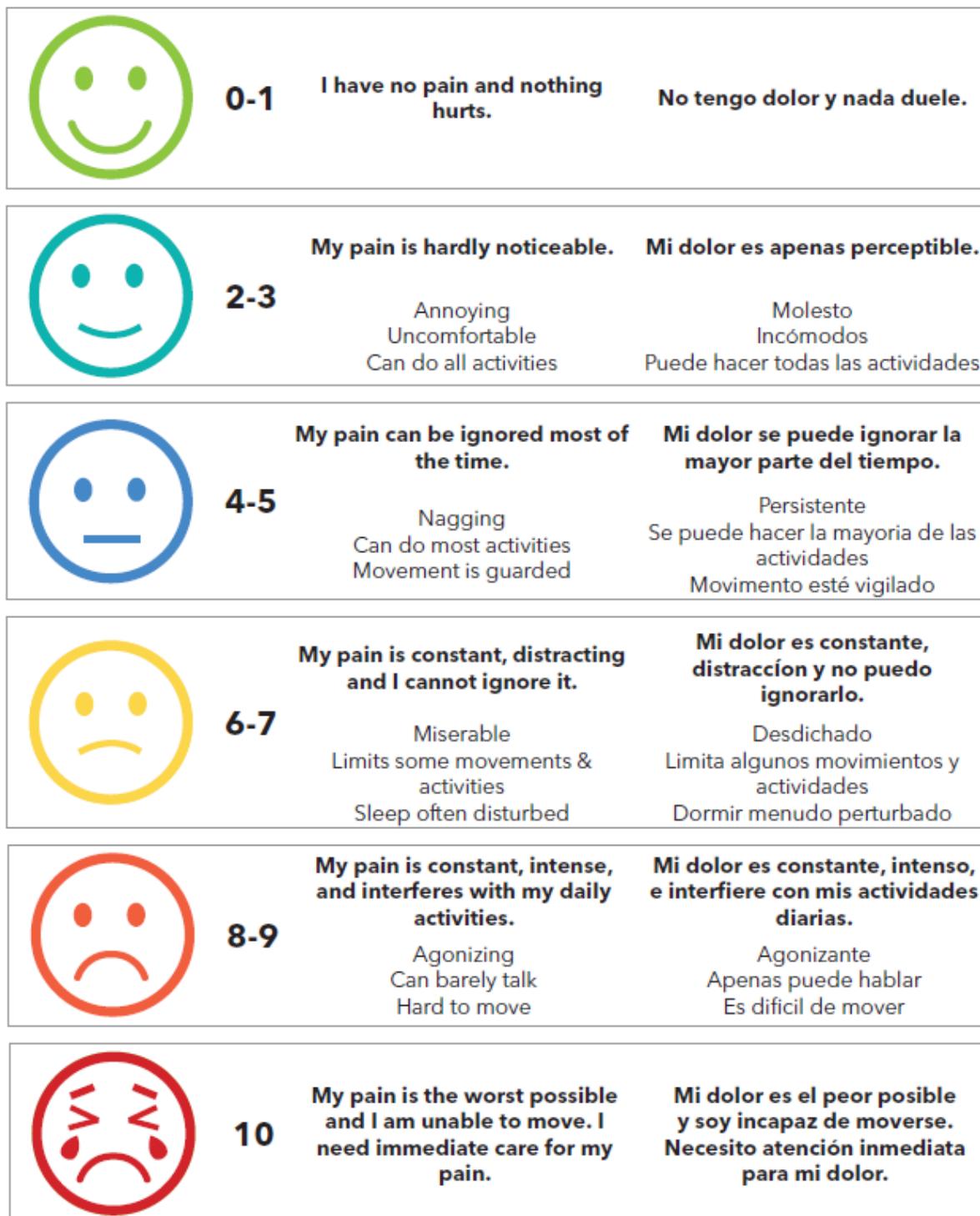
Spanish language translation (see attached, other languages available on our website www.herayahealth.com).

These scales can also be adapted to other physical symptoms, e.g. discomfort, stiffness, perception of breathing capacity for asthmatics.

When implementing these instruments, an initial evaluation of a new member or existing member with a new problem is appropriate and at intervals thereafter consistent with the type of condition and the member's response to care. For example, a more acute condition would likely see more rapid progress and re-measuring in days is reasonable compared to a chronic condition where change may occur more slowly and re-measuring in weeks may be more appropriate. Similarly, these numbers can be used to set treatment goals, e.g. reduce pain by 50% in 2 weeks.

Best Practices in Clinical Record Keeping: Face Pain Scale

Tell Us About Your Pain / Háblenos de su dolor...



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Best Practices in Clinical Record Keeping: Documenting Diagnostic Imaging

Introduction

Complete and thorough documentation of diagnostic imaging studies is an important part of the clinical record. The clinical history and examination findings should document the indications for the imaging that is conducted.

Identification

Reports of studies should always incorporate complete identifiers including:

- Member name, age/date of birth, sex
- Facility name, address, phone number
- Ordering provider name
- Date of study
- Area of study and views obtained

Report

In-house studies and interpretation of outside films should be an accurate description of all significant diagnostic imaging findings. An “impression” contains a summary of important findings and should contribute to the diagnosis and guide the treatment plan.

Recommendations for further imaging studies, other tests or specialty referral should be noted.

Outside Studies

Studies that are conducted and interpreted at another facility should be documented by reports from that facility. These reports should be reviewed, initialed and dated upon receipt. If outside studies are not documented, interpretation should be obtained from a qualified clinician.

Best Practices in Clinical Record Keeping: Documenting the Diagnosis

Introduction

The clinical record must contain documentation of the physician's assessment of the member's condition that is being treated.

Documenting the Diagnosis

The diagnosis itself must be consistent with and supported by the member's presentation, examination, laboratory, and diagnostic imaging findings. Initially the diagnosis is often only the diagnostic impression or working diagnosis. On follow-up visits the diagnosis should be confirmed as the clinical thought process continues.

Documentation of return follow up visits (usually in the "A" portion of the SOAP note) must include a statement of the diagnosis that reflects changes in the member's condition as a response to time, treatment, and other interim events (e.g., "Cervical strain, resolving" or "fatigue, improving"). The "A" should be updated as necessary to be an accurate portrayal of the member's present condition.

Diagnosis codes used on a health insurance claim form must be supported by the information in the member clinical record.

ICD-10-CM

Transition to ICD-10-CM occurred October 1, 2015. The diagnosis codes in ICD-10 are more specific and more detailed. For example, left and right-side conditions (e.g., extremity conditions) are now 2 different diagnoses. And there are different diagnoses for certain conditions seen at an initial encounter, in follow up "subsequent" encounters and as a sequela. As with ICD-9 codes, the clinical record must support the code used to document the condition or as used on an insurance claim form.

Note: Some IH providers are prohibited by law from making a differential diagnosis and therefore, this "best practice" recommendation may not apply to all. However, many diagnosis codes are symptoms only and do not imply that the provider has made a "differential diagnosis." For example, "neck pain/cervicalgia" is M54.2 (ICD-10).

Best Practices in Clinical Record Keeping: Documenting Modalities and Procedures

Introduction

Providers need to accurately record clinical information when providing or performing physical therapy modalities and procedures. Standards for “best practices” rely on these records to establish the clinical necessity and effectiveness of any given modality or procedure, aid in the determination of member outcomes management, help with continuity of member care, and aid in the reduction of malpractice risk.

These services are broken up into three broad categories:

- Supervised (CPT codes 97010 – 97028) – these are limited to one unit per member encounter per day regardless of time or region.
- Constant Attendance (CPT codes 97032 – 97039) – these are time based and require the provider to be present during the administration, application, or performance of the modality.
- Therapeutic Procedures (CPT codes 97110 – 97546) – these require direct member – provider interaction; these are also time based.

Clinical documentation for these services should include a brief explanation of the necessity of the service, the nature of the modality or procedure (ultrasound, interferential electrical stimulation, massage, myofascial release, etc.), settings – if appropriate (e.g. pulsed vs. continuous ultrasound), location of application by region or segment (as specific as possible), duration, and result.

When billing any time-based modality or procedure, certain rules apply. While the AMA CPT Code Book defines time as a 15-minute unit, actual practice does not always fit such rigid parameters. Billing methods² for time-based services, including physical therapy modalities and procedures allow for some flexibility.

While one unit of time is 15 minutes, the individual service is allowed to vary between 8 minutes (just above the midpoint between 0 and 15) to 22 minutes (just below the midpoint between 15 and 30). Thus, a single unit of service may be billed when the involved time reaches 8 minutes.

² CMS Physical and Occupational Therapy Billing Manual, Center for Medicare and Medicaid Services, 2010, 2012

When more than a single unit is rendered or when other time-based modalities or procedures are performed during the same encounter, the provider must account for the total time involved in rendering these services. If two time-based services are performed sequentially, billing would be dependent on the total time of service. As an example, 8 minutes of ultrasound (CPT code 97035) followed by 8 minutes of attended electrical stimulation (CPT code 97032) totals only 16 minutes of time-based services. While if each were performed separately on different dates of service, one unit of time could be billed for each code. However, since the two procedures are performed in the same visit, only one unit (8 to 22 minutes) can be billed. In such a case, it would be permitted to bill for the modality or procedure with the higher associated fee. If the fees are the same, bill for the one requiring slightly more time than the other. If all aspects are equal, the decision is left to the provider to bill for one or the other; however, the clinical documentation needs to reflect the specific services performed during the member encounter.

When multiple units of service are billed, only the last unit of service is subject to the range of time adjustment. All other units billed are based on the 15-minute definition. Two units of service would require 15 minutes for the first unit; the second unit could range between 8 and 22 minutes (total time of service would be from a low of 23 to a high of 37 minutes). Three units of service would require 30 minutes for the first two units; the third unit could range between 8 and 22 minutes (total time of service would be from a low of 38 minutes to a high of 52 minutes). The same method of calculation is used as additional units of modalities or procedures are added.

It is incumbent on the provider to document the time elements described above in such a manner that allows easy determination of when threshold parameters are met.

Best Practices in Clinical Record Keeping: Signature Authentication

This “Best Practices” guideline provides a summary of requirements and recommendations for authentication of signatures in medical records. As a provider of clinical services, your chart note is the mechanism for memorializing the interaction with the member during that visit. The signature at the end of the note is a symbol which confirms that the signer authored, reviewed, and approved the content of the entry. A proper signature contributes to the integrity of the note as a legal record. Historically, medical records were maintained on paper and relied on handwritten signatures with all of the inherent legibility problems caused by busy providers. With the advent of electronic medical records (EMR), certain other concerns for validity and integrity of signatures have emerged.

The Centers for Medicare & Medicaid Services (CMS) has laid out the criteria for a valid signature, whether handwritten, stamped, or electronic:

- Services that are provided or ordered must be authenticated by the ordering practitioner;
- Signatures are handwritten, electronic, or stamped (stamped signatures are only permitted in the case of an author with a physical disability who can provide proof to a CMS contractor of an inability to sign due to a disability); and
- Signatures are legible.³

Handwritten Signatures

The signature must be legible. This can be achieved with a legible first and last name, a legible first initial and legible last name. Alternatively, an illegible signature or initials over a typed/printed legible identification of the author; illegible signature where the letterhead, addressograph or other information on the page indicates the identity of the signatory; where multiple providers are listed the author of record is specifically identified. A signature log may be used to associate a provider’s name with an illegible signature. The log is typically a typed list of the provider(s) who contribute to the medical record. Each name is tied to the corresponding handwritten signature.⁴

Electronic Signatures

Adoption of EMR systems has caused an evolution in the concepts of the electronic signature (e-signature). At this point in time (2016) there is no single overarching standard for e-

³ CMS [Complying with Medicare Signature Requirements](#)

⁴ HC Pro.com [Just Coding News: Outpatient, August 11, 2010](#)

signatures. One generally recognized health information technology (HIT) standards organization is The Health Level Seven (HL7) [see sidebar]. HL7 defines “authentication” as “the security process of verifying a user’s identity that authorizes the individual to access the system (e.g., the sign-on process).” Whereas “attestation” is “the act of applying an e-signature to the content, showing authorship and legal responsibility for a particular unit of information.”⁵

For a signature to be valid, systems and software products must include protections against modifications (e.g. time and date stamp), and administrative safeguards should be applied that correspond to standards and laws, e.g. using signature and secure login functions appropriately. Best practice would include the following elements: full printed name of the author at the end of the entry, date and time, the digitized signature or signature statement, e.g. electronically signed by, signed by, authenticated by, reviewed by, etc. with the author’s credentials. For example, “Authenticated by Jane Doe, DC on 10/30/2015 at 1:00 pm”.⁶

The Code of Federal Regulations Title 21 of the Food and Drug Administration provides guidance that define “the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.”⁶

Electronic signatures typically found in EMRs include:

- Digitized signature which is an electronic representation of a handwritten signature. It is considered to be the weakest form of signature. The digitized signature can be used by anyone to forge a document.
- E-signatures that use “button, PIN, biometric or token” methodology are more secure and strengthen the integrity of the record since use of the signature is dependent on the user having a unique identifier such as a PIN or user/password combination. This guards against unauthorized use of the signature.

⁵ Health Level Seven. HL7 EHR System Records Management and Evidentiary Support Functional Profile 2009. Available online at www.hl7.org.

⁶ CFR Title 21 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

- The strongest e-signature is a “digital signature.” “...a digital signature is a cryptographic signature (a digital key) that authenticates the user, provides nonrepudiation, and ensures message integrity. This is the strongest signature because it protects the signature by a type of tamper-proof seal that breaks if the message content were to be altered.”⁷ This highest level of e-signature effectively “locks” a chart entry and prevents alteration or amendment to the content after the digital signature has been applied. When using an EMR system, be aware of the level of security and integrity that is built into the system’s e-signature.

Health Level Seven International (HL7) “is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.”

[More here.](#)

Summary

- A legible signature provides the best level of integrity of a chart note as a legal record.
- Every provider of service (physician, therapist, medical/chiropractic assistant, etc.) should sign the note documenting their service.
- Electronic signatures (e-signature) have varying levels of security and integrity. Be sure that you are aware of the strength of the e-signature in your EMR system.

⁷ AHIMA http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_045551.hcsp?dDocName=bok1_045551

De-Identifying Clinical Records for Quality Improvement

Introduction

Heraya sometimes requires you to submit clinical records for various purposes such as record keeping quality improvement. When responding to these requests, it is imperative that you are compliant with Federal rules that protect member confidentiality. **Note: These rules do not apply to clinical records submitted to support billing, for Treatment Extension Requests, appeals and other aspects of payment.**

Why do I need to de-identify my clinical records?

The Health Insurance Portability and Accountability Act (HIPAA) requires covered entities to protect member-specific health information, known as Protected Health Information (PHI). However, HIPAA permits the use or disclosure of properly de-identified health information, as it is no longer considered PHI.

What does "de-identify" mean?

The term "de-identify" is from HIPAA and refers to redacting clinical record so that no one can tell who the information is about. PHI is considered to be properly de-identified if all of the 18 specified identifiers are redacted. These 18 identifiers are listed on the next page.

If I am not a covered entity as defined by HIPAA, do I still need to de-identify my clinical records sent to Heraya?

While you may or may not be a "covered entity," Heraya recommends that you take this precautionary measure when responding to requests for clinical records for quality management purposes.

Where can I obtain more information on de-identifying PHI?

The Department of Health and Human Services is the federal agency responsible for administering HIPAA. Below is a link to their website which speaks specifically to this topic:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html>

If I have questions, who can I call at Heraya?

The Clinical Services Department may be contacted at 503-203-8333, extension 124.

The following are the 18 identifiers that create the definition of “individually identifiable” and can be used to identify a specific individual.

1. Names of members, spouses, relatives
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes?, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census (a) the geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (b) the initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Day and month elements of dates directly related to an individual, such as birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of “age 90 or older.” **Note: this does not apply to dates of service in chart notes.**
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) addresses
16. Biometric identifiers, including finger and voice prints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code