AUDITING RESOURCES

technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* New Collection;

Title of Information Collection: Employee Building Pass Application and File;

Form No.: HCFA–730 & 182 (OMB# 0938–NEW);

Use: The purpose of this system and the forms are to control United States Government Building Passes issued to all HCFA employees and non-HCFA employees who require continuous access to HCFA buildings in Baltimore and other HCFA and HHS buildings.;

Frequency: Other; as needed;

Affected Public: Federal Government, and business or other for-profit;

Number of Respondents: 150;

Total Annual Responses: 150;

Total Annual Hours: 37.50.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Limitation on Liability and Information Collection Requirements Referenced in 42 CFR 411.404, 411.406, and 411.408;

Form No.: HCFA–R–77 (OMB# 0938–0465);

Use: The Medicare program requires to provide written notification of noncovered services to beneficiaries by the providers, practitioners, and suppliers. The notification gives the beneficiary, provider, practitioner, or supplier knowledge that Medicare will not pay for items or services mentioned in the notification. After this notification, any future claim for the same or similar services will not be paid by the program and the affected parties will be liable for the noncovered services.;

Frequency: Other; as needed;

Affected Public: Individuals or households;

Number of Respondents: 890,826;

Total Annual Responses: 3,563,304;

Total Annual Hours: 296,942.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 11, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–25581 Filed 10–4–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program for Individual and Small Group Physician Practices

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Individual and Small Group Physician Practices developed by the Office of Inspector General (OIG). The OIG has previously developed and published voluntary compliance program guidance focused on several other areas and aspects of the health care industry. We believe that the development and issuance of this voluntary compliance program guidance for individual and small group physician practices will serve as a positive step towards assisting providers in preventing the submission of erroneous claims or engaging in unlawful conduct involving the Federal health care programs.

FOR FURTHER INFORMATION CONTACT: Kimberly Brandt, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances is a major initiative of the OIG in its effort to engage the private health care community in preventing the submission of erroneous claims and in combating fraudulent conduct. In the past several years, the OIG has developed and issued compliance program guidances directed at a variety of segments in the health care industry. The development of these types of compliance program guidances is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

Copies of these compliance program guidances can be found on the OIG web site at http://www.hhs.gov/oig.

Developing the Compliance Program Guidance for Individual and Small Group Physician Practices

On September 8, 1999, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for individual and small group physician practices (64 FR 48846). In response to that solicitation notice, the OIG received 83 comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidance and Special Fraud Alerts, in developing a guidance for individual and small group physician practices. In addition, we have consulted with the Health Care Financing Administration and the Department of Justice. In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft guidance for individual and small group physician practices was published in the **Federal Register** on June 12, 2000 (65 FR 36818) for further comments and recommendations.

Components of an Effective Compliance Program

This compliance program guidance for individual and small group physician practices contains seven components that provide a solid basis upon which a physician practice can create a voluntary compliance program:

- Conducting internal monitoring and auditing;
- Implementing compliance and practice standards;
- Designating a compliance officer or contact;
- Conducting appropriate training and education;
- Responding appropriately to detected offenses and developing corrective action;
- Developing open lines of communication; and
- Enforcing disciplinary standards through well-publicized guidelines.

Similar components have been contained in previous guidances issued by the OIG. However, unlike other guidances issued by OIG, this guidance for physicians does not suggest that physician practices implement all seven components of a full scale compliance program. Instead, the guidance emphasizes a step by step approach to follow in developing and implementing a voluntary compliance program. This change is in recognition of the financial and staffing resource constraints faced

by physician practices. The guidance should not be viewed as mandatory or as an all-inclusive discussion of the advisable components of a compliance program. Rather, the document is intended to present guidance to assist physician practices that voluntarily choose to develop a compliance program.

Office of Inspector General's Compliance Program Guidance for Individual and Small Group Physician Practices

I. Introduction

This compliance program guidance is intended to assist individual and small group physician practices (''physician practices'') [1] in developing a voluntary compliance program that promotes adherence to statutes and regulations applicable to the Federal health care programs (''Federal health care program requirements''). The goal of voluntary compliance programs is to provide a tool to strengthen the efforts of health care providers to prevent and reduce improper conduct. These programs can also benefit physician practices[2] by helping to streamline business operations.

Many physicians have expressed an interest in better protecting their practices from the potential for erroneous or fraudulent conduct through the implementation of voluntary compliance programs. The Office of Inspector General (OIG) believes that the great majority of physicians are honest and share our goal of protecting the integrity of Medicare and other Federal health care programs. To that end, all health care providers have a duty to ensure that the claims submitted to Federal health care programs are true and accurate. The development of voluntary compliance programs and the active application of compliance principles in physician practices will go a long way toward achieving this goal.

Through this document, the OIG provides its views on the fundamental components of physician practice compliance programs, as well as the principles that a physician practice might consider when developing and implementing a voluntary compliance program. While this document presents basic procedural and structural guidance for designing a voluntary compliance program, it is not in and of itself a compliance program. Indeed, as recognized by the OIG and the health care industry, there is no ''one size fits all'' compliance program, especially for physician practices. Rather, it is a set of guidelines that physician practices can consider if they choose to develop and implement a compliance program.

As with the OIG's previous guidance, [3] these guidelines are not mandatory. Nor do they represent an all-inclusive document containing all components of a compliance program. Other OIG outreach efforts, as well as other Federal agency efforts to promote compliance,[4] can also be used in developing a compliance program. However, as explained later, if a physician practice adopts a voluntary and active compliance program, it may well lead to benefits for the physician practice.

A. Scope of the Voluntary Compliance Program Guidance

This guidance focuses on voluntary compliance measures related to claims submitted to the Federal health care programs. Issues related to private payor claims may also be covered by a compliance plan if the physician practice so desires.

The guidance is also limited in scope by focusing on the development of voluntary compliance programs for individual and small group physician practices. The difference between a small practice and a large practice cannot be determined by stating a particular number of physicians. Instead, our intent in narrowing the guidance to the small practices subset was to provide guidance to those physician practices whose financial or staffing resources would not allow them to implement a full scale, institutionally structured compliance program as set forth in the Third Party Medical Billing Guidance or other previously released OIG guidance. A compliance program can be an important tool for physician practices of all sizes and does not have to be costly, resource-intensive or time-intensive.

B. Benefits of a Voluntary Compliance Program

The OIG acknowledges that patient care is, and should be, the first priority of a physician practice. However, a practice's focus on patient care can be enhanced by the adoption of a voluntary compliance program. For example, the increased accuracy of documentation that may result from a compliance program will actually assist in enhancing patient care. The OIG believes that physician practices can realize numerous other benefits by implementing a compliance program. A well-designed compliance program can:

- Speed and optimize proper payment of claims;
- Minimize billing mistakes;
- Reduce the chances that an audit will be conducted by HCFA or the OIG; and
- Avoid conflicts with the self-referral and anti-kickback statutes.

The incorporation of compliance measures into a physician practice should not be at the expense of patient care, but instead should augment the ability of the physician practice to provide quality patient care.

Voluntary compliance programs also provide benefits by not only helping to prevent erroneous or fraudulent claims, but also by showing that the physician practice is making additional good faith efforts to submit claims appropriately. Physicians should view compliance programs as analogous to practicing preventive medicine for their practice. Practices that embrace the active application of compliance principles in their practice culture and put efforts towards compliance on a continued basis can help to prevent problems from occurring in the future.

A compliance program also sends an important message to a physician practice's employees that while the practice recognizes that mistakes will occur, employees have an affirmative, ethical duty to come forward and report erroneous or fraudulent conduct, so that it may be corrected.

[1] For the purpose of this guidance, the term ''physician'' is defined as: (1) a doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a podiatrist; (4) an optometrist; or (5) a chiropractor, all of whom must be appropriately licensed by the State. 42 U.S.C. 1395x(r).

[2] Much of this guidance can also apply to other independent practitioners, such as psychologists, physical therapists, speech language pathologists, and occupational therapists.

[3] Currently, the OIG has issued compliance program guidance for the following eight industry sectors: hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, Medicare+Choice organizations offering coordinated care plans, and nursing facilities. The guidance listed here and referenced in this document is available on the OIG web site at http://www.hhs.gov/oig in the Electronic Reading Room or by calling the OIG Public Affairs office at (202) 619–1343.

[4] The OIG has issued Advisory Opinions responding to specific inquiries concerning the application of the OIG's authorities, in particular, the anti-kickback statute, and Special Fraud Alerts setting forth activities that raise legal and enforcement issues. These documents, as well as reports from the OIG's Office of Audit Services and Office of Evaluation and Inspections can be obtained via the Internet address or phone number provided in Footnote 3. Physician practices can also review the Health Care Financing Administration (HCFA) web site on the Internet at http://www.hcfa.gov, for up-to-date regulations, manuals, and program memoranda related to the Medicare and Medicaid programs.

C. Application of Voluntary Compliance Program Guidance

The applicability of these recommendations will depend on the circumstances and resources of the particular physician practice.

Each physician practice can undertake reasonable steps to implement compliance measures, depending on the size and resources of that practice. Physician practices can rely, at least in part, upon standard protocols and current practice procedures to develop an appropriate compliance program for that practice. In fact, many physician practices already have established the framework of a compliance program without referring to it as such.

D. The Difference Between ''Erroneous'' and ''Fraudulent'' Claims To Federal Health Programs

There appear to be significant misunderstandings within the physician community regarding the critical differences between what the Government views as innocent ''erroneous'' claims on the one hand and ''fraudulent'' (intentionally or recklessly false) health care claims on the other. Some physicians feel that Federal law enforcement agencies have maligned medical professionals, in part, by a perceived focus on innocent billing errors. These physicians are under the impression that innocent billing errors can subject them to civil penalties, or even jail. These impressions are mistaken.

To address these concerns, the OIG would like to emphasize the following points. First, the OIG does not disparage physicians, other medical professionals or medical enterprises. In our view, the great majority of physicians are working ethically to render high quality medical care and to submit proper claims.

Second, under the law, physicians are not subject to criminal, civil or administrative penalties for innocent errors, or even negligence. The Government's primary enforcement tool, the civil False Claims Act, covers only offenses that are committed with actual knowledge of the falsity of the claim, reckless disregard, or deliberate ignorance of the falsity of the claim.[5] The False Claims Act does not encompass mistakes, errors, or negligence. The Civil Monetary Penalties Law, an administrative remedy, similar in scope and effect to the False Claims Act, has exactly the same standard of proof.[6] The OIG is very mindful of the difference between innocent errors (''erroneous claims'') on one hand, and reckless or intentional conduct (''fraudulent claims'') on the other. For criminal penalties, the standard is even higher—criminal intent to defraud must be proved beyond a reasonable doubt.

Third, even ethical physicians (and their staffs) make billing mistakes and errors through inadvertence or negligence. When physicians discover that their billing errors, honest mistakes, or negligence result in erroneous claims, the physician practice should return the funds erroneously claimed, but without penalties. In other words, absent a violation of a civil, criminal or administrative law, erroneous claims result only in the return of funds claimed in error.

Fourth, innocent billing errors are a significant drain on the Federal health care programs. All parties (physicians, providers, carriers, fiscal intermediaries, Government agencies, and beneficiaries) need to work cooperatively to reduce the overall error rate.

Finally, it is reasonable for physicians (and other providers) to ask: what duty do they owe the Federal health care programs? The answer is that all health care providers have a duty to reasonably ensure that the claims submitted to Medicare and other Federal health care programs are true and accurate. The OIG continues to engage the provider community in an extensive, good faith effort to work cooperatively on voluntary compliance to minimize errors and to prevent potential penalties for improper billings before they occur. We encourage all physicians and other providers to join in this effort.

II. Developing a Voluntary Compliance Program

A. The Seven Basic Components of a Voluntary Compliance Program

The OIG believes that a basic framework for any voluntary compliance program begins with a review of the seven basic components of an effective compliance program. A review of these components provides physician practices with an overview of the scope of a fully developed and implemented compliance program. The following list of components, as set forth in previous OIG compliance program guidances, can form the basis of a voluntary compliance program for a physician practice:

- Conducting internal monitoring and auditing through the performance of periodic audits;
- Implementing compliance and practice standards through the development of written standards and procedures;
- Designating a compliance officer or contact(s) to monitor compliance efforts and enforce practice standards;
- Conducting appropriate training and education on practice standards and procedures;
- Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate Government entities;
- Developing open lines of communication, such as (1) discussions at staff meetings regarding how to avoid erroneous or fraudulent conduct and (2) community bulletin boards, to keep practice employees updated regarding compliance activities; and
- Enforcing disciplinary standards through well-publicized guidelines.

These seven components provide a solid basis upon which a physician practice can create a compliance program. The OIG acknowledges that full implementation of all components may not be feasible for all physician practices. Some physician practices may never fully implement all of the components. However, as a first step, physician practices can begin by adopting only those components which, based on a practice's specific history with billing problems and other compliance issues, are most likely to provide an identifiable benefit.

The extent of implementation will depend on the size and resources of the practice. Smaller physician practices may incorporate each of the components in a manner that best suits the practice. By contrast, larger physician practices often have the means to incorporate the components in a more systematic manner. For example, larger physician practices can use both this guidance and the Third-Party Medical Billing Compliance Program Guidance, which provides a more detailed compliance program structure, to create a compliance program unique to the practice.

The OIG recognizes that physician practices need to find the best way to achieve compliance for their given circumstances. Specifically, the OIG encourages physician practices to participate in other provider's compliance programs, such as the compliance programs of the hospitals or other settings in which the physicians practice. Physician Practice Management companies also may serve as a source of compliance program guidance. A physician practice's participation in such compliance programs could be a way, at least partly,

[5] 31 U.S.C. 3729.

[6] 42 U.S.C. 1320a–7a.

to augment the practice's own compliance efforts.

The opportunities for collaborative compliance efforts could include participating in training and education programs or using another entity's policies and procedures as a template from which the physician practice creates its own version. The OIG encourages this type of collaborative effort, where the content is appropriate to the setting involved (i.e., the training is relevant to physician practices as well as the sponsoring provider), because it provides a means to promote the desired objective without imposing excessive burdens on the practice or requiring physicians to undertake duplicative action. However, to prevent possible anti-kickback or self-referral issues, the OIG recommends that physicians consider limiting their participation in a sponsoring provider's compliance program to the areas of training and education or policies and procedures.

The key to avoiding possible conflicts is to ensure that the entity providing compliance services to a physician practice (its referral source) is not perceived as nor is it operating the practice compliance program at no charge. For example, if the sponsoring entity conducted claims review for the physician practice as part of a compliance program or provided compliance oversight without charging the practice fair market value for those services, the anti-kickback and Stark self-referral laws would be implicated. The payment of fair market value by referral sources for compliance services will generally address these concerns.

B. Steps for Implementing a Voluntary Compliance Program

As previously discussed, implementing a voluntary compliance program can be a multi-tiered process. Initial development of the compliance program can be focused on practice risk areas that have been problematic for the practice such as coding and billing. Within this area, the practice should examine its claims denial history or claims that have resulted in repeated overpayments, and identify and correct the most frequent sources of those denials or overpayments. A review of claim denials will help the practice scrutinize a significant risk area and improve its cash flow by submitting correct claims that will be paid the first time they are submitted. As this example illustrates, a compliance program for a physician practice often makes sound business sense.

The following is a suggested order of the steps a practice could take to begin the development of a compliance program. The steps outlined below articulate all seven components of a compliance program and there are numerous suggestions for implementation within each component. Physician practices should keep in mind, as stated earlier, that it is up to the practice to determine the manner in which and the extent to which the practice chooses to implement these voluntary measures.

Step One: Auditing and Monitoring

An ongoing evaluation process is important to a successful compliance program. This ongoing evaluation includes not only whether the physician practice's standards and procedures are in fact current and accurate, but also whether the compliance program is working, *i.e.*, whether individuals are properly carrying out their responsibilities and claims are submitted appropriately. Therefore, an audit is an excellent way for a physician practice to ascertain what, if any, problem areas exist and focus on the risk areas that are associated with those problems. There are two types of reviews that can be performed as part of this evaluation: (1) A standards and procedures review; and (2) a claims submission audit.

1. Standards and Procedures

It is recommended that an individual(s) in the physician practice be charged with the responsibility of periodically reviewing the practice's standards and procedures to determine if they are current and complete. If the standards and procedures are found to be ineffective or outdated, they should be updated to reflect changes in Government regulations or compendiums generally relied upon by physicians and insurers (*i.e.*, changes in Current Procedural Terminology (CPT) and ICD–9–CM codes).

2. Claims Submission Audit

In addition to the standards and procedures themselves, it is advisable that bills and medical records be reviewed for compliance with applicable coding, billing and documentation requirements. The individuals from the physician practice involved in these self-audits would ideally include the person in charge of billing (if the practice has such a person) and a medically trained person (*e.g.*, registered nurse or preferably a physician (physicians can rotate in this position)). Each physician practice needs to decide for itself whether to review claims retrospectively or concurrently with the claims submission. In the Third-Party Medical Billing Compliance Program Guidance, the OIG recommended that a baseline, or ''snapshot,'' be used to enable a practice to judge over time its progress in reducing or eliminating potential areas of vulnerability. This practice, known as ''benchmarking,'' allows a practice to chart its compliance efforts by showing a reduction or increase in the number of claims paid and denied.

The practice's self-audits can be used to determine whether:

- Bills are accurately coded and accurately reflect the services provided (as documented in the medical records);
- Documentation is being completed correctly;
- Services or items provided are reasonable and necessary; and
- Any incentives for unnecessary services exist.

A baseline audit examines the claim development and submission process, from patient intake through claim submission and payment, and identifies elements within this process that may contribute to non-compliance or that may need to be the focus for improving execution.[7] This audit will establish a consistent methodology for selecting and examining records, and this methodology will then serve as a basis for future audits.

There are many ways to conduct a baseline audit. The OIG recommends that claims/services that were submitted and paid during the initial three months after implementation of the education and training program be examined, so as to give the physician practice a benchmark against which to measure future compliance effectiveness.

Following the baseline audit, a general recommendation is that periodic audits be conducted at least once each year to ensure that the compliance program is being followed. Optimally, a randomly selected number of medical records could be reviewed to ensure that the coding was performed accurately. Although there is no set formula to how many medical records should be reviewed, a basic guide is five or more medical records per Federal payor (*i.e.*, Medicare, Medicaid), or five to ten medical records per physician. The OIG realizes that physician practices receive reimbursement from a number of different payors, and we would encourage a physician practice's auditing/monitoring process to consist of a review of claims from all Federal payors from which the practice receives reimbursement. Of course, the larger the sample size, the larger the comfort level

[7] *See* Appendix D.II. referencing the Provider Self-Disclosure Protocol for information on how to conduct a baseline audit.

the physician practice will have about the results. However, the OIG is aware that this may be burdensome for some physician practices, so, at a minimum, we would encourage the physician practice to conduct a review of claims that have been reimbursed by Federal health care programs.

If problems are identified, the physician practice will need to determine whether a focused review should be conducted on a more frequent basis. When audit results reveal areas needing additional information or education of employees and physicians, the physician practice will need to analyze whether these areas should be incorporated into the training and educational system.

There are many ways to identify the claims/services from which to draw the random sample of claims to be audited. One methodology is to choose a random sample of claims/services from either all of the claims/services a physician has received reimbursement for or all claims/services from a particular payor. Another method is to identify risk areas or potential billing vulnerabilities. The codes associated with these risk areas may become the universe of claims/services from which to select the sample. The OIG recommends that the physician practice evaluate claims/services selected to determine if the codes billed and reimbursed were accurately ordered, performed, and reasonable and necessary for the treatment of the patient.

One of the most important components of a successful compliance audit protocol is an appropriate response when the physician practice identifies a problem. This action should be taken as soon as possible after the date the problem is identified. The specific action a physician practice takes should depend on the circumstances of the situation. In some cases, the response can be as straight forward as generating a repayment with appropriate explanation to Medicare or the appropriate payor from which the overpayment was received. In others, the physician practice may want to consult with a coding/billing expert to determine the next best course of action. There is no boilerplate solution to how to handle problems that are identified.

It is a good business practice to create a system to address how physician practices will respond to and report potential problems. In addition, preserving information relating to identification of the problem is as important as preserving information that tracks the physician practice's reaction to, and solution for, the issue.

Step 2: Establish Practice Standards and Procedures

After the internal audit identifies the practice's risk areas, the next step is to develop a method for dealing with those risk areas through the practice's standards and procedures. Written standards and procedures are a central component of any compliance program. Those standards and procedures help to reduce the prospect of erroneous claims and fraudulent activity by identifying risk areas for the practice and establishing tighter internal controls to counter those risks, while also helping to identify any aberrant billing practices. Many physician practices already have something similar to this called ''practice standards'' that include practice policy statements regarding patient care, personnel matters and practice standards and procedures on complying with Federal and State law.

The OIG believes that written standards and procedures can be helpful to all physician practices, regardless of size and capability. If a lack of resources to develop such standards and procedures is genuinely an issue, the OIG recommends that a physician practice focus first on those risk areas most likely to arise in its particular practice.[8] Additionally, if the physician practice works with a physician practice management company (PPMC), independent practice association (IPA), physician-hospital organization, management services organization (MSO) or third-party billing company, the practice can incorporate the compliance standards and procedures of those entities, if appropriate, into its own standards and procedures. Many physician practices have found that the adoption of a third party's compliance standards and procedures, as appropriate, has many benefits and the result is a consistent set of standards and procedures for a community of physicians as well as having just one entity that can then monitor and refine the process as needed. This sharing of compliance responsibilities assists physician practices in rural areas that do not have the staff to perform these functions, but do belong to a group that does have the resources. Physician practices using another entity's compliance materials will need to tailor those materials to the physician practice where they will be applied.

Physician practices that do not have standards or procedures in place can develop them by: (1) Developing a written standards and procedures manual; and (2) updating clinical forms periodically to make sure they facilitate and encourage clear and complete documentation of patient care. A practice's standards could also identify the clinical protocol(s), pathway(s), and other treatment guidelines followed by the practice.

Creating a resource manual from publicly available information may be a cost-effective approach for developing additional standards and procedures. For example, the practice can develop a ''binder'' that contains the practice's written standards and procedures, relevant HCFA directives and carrier bulletins, and summaries of informative OIG documents (*e.g.,* Special Fraud Alerts, Advisory Opinions, inspection and audit reports).[9] If the practice chooses to adopt this idea, the binder should be updated as appropriate and located in a readily accessible location.

If updates to the standards and procedures are necessary, those updates should be communicated to employees to keep them informed regarding the practice's operations. New employees can be made aware of the standards and procedures when hired and can be trained on their contents as part of their orientation to the practice. The OIG recommends that the communication of updates and training of new employees occur as soon as possible after either the issuance of a new update or the hiring of a new employee.

1. Specific Risk Areas

The OIG recognizes that many physician practices may not have in place standards and procedures to prevent erroneous or fraudulent conduct in their practices. In order to develop standards and procedures, the physician practice may consider what types of fraud and abuse related topics need to be addressed based on its specific needs. One of the most important things in making that determination is a listing of risk areas where the practice may be vulnerable.

To assist physician practices in performing this initial assessment, the OIG has developed a list of four potential risk areas affecting physician practices. These risk areas include: (a) Coding and billing; (b) reasonable and necessary services; (c) documentation;

[8] Physician practices with laboratories or arrangements with third-party billing companies can also check the risk areas included in the OIG compliance program guidance for those industries.

[9] The OIG and HCFA are working to compile a list of basic documents issued by both entities that could be included in such a binder. We expect to complete this list later this fall, and will post it on the OIG and HCFA web sites, as well as publicize this list to physician organizations and representatives (information on how to contact the OIG is contained in Footnote 3; HCFA information can be obtained at www.hcfa.gov/medlearn or by calling 1–800–MEDICARE).

and (d) improper inducements, kickbacks and self-referrals. This list of risk areas is not exhaustive, or all-encompassing. Rather, it should be viewed as a starting point for an internal review of potential vulnerabilities within the physician practice.[10] The objective of such an assessment is to ensure that key personnel in the physician practice are aware of these major risk areas and that steps are taken to minimize, to the extent possible, the types of problems identified. While there are many ways to accomplish this objective, clear written standards and procedures that are communicated to all employees are important to ensure the effectiveness of a compliance program. Specifically, the following are discussions of risk areas for physician practices:[11]

a. Coding and Billing. A major part of any physician practice's compliance program is the identification of risk areas associated with coding and billing. The following risk areas associated with billing have been among the most frequent subjects of investigations and audits by the OIG:

- Billing for items or services not rendered or not provided as claimed;[12]
- Submitting claims for equipment, medical supplies and services that are not reasonable and necessary;[13]
- Double billing resulting in duplicate payment;[14]
- Billing for non-covered services as if covered;[15]
- Knowing misuse of provider identification numbers, which results in improper billing;[16]
- Unbundling (billing for each component of the service instead of billing or using an all-inclusive code);[17]
- Failure to properly use coding modifiers;[18]
- Clustering;[19] and
- Upcoding the level of service provided.[20]

The physician practice written standards and procedures concerning proper coding reflect the current reimbursement principles set forth in applicable statutes, regulations[21] and Federal, State or private payor health care program requirements and should be developed in tandem with coding and billing standards used in the physician practice. Furthermore, written standards and procedures should ensure that coding and billing are based on medical record documentation. Particular attention should be paid to issues of appropriate diagnosis codes and individual Medicare Part B claims (including documentation guidelines for evaluation and management services).[22] A physician practice can also institute a policy that the coder and/or physician review all rejected claims pertaining to diagnosis and procedure codes. This step can facilitate a reduction in similar errors.

b. Reasonable and Necessary Services. A practice's compliance program may provide guidance that claims are to be submitted only for services that the physician practice finds to be reasonable and necessary in the particular case. The OIG recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, a physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary.[23]

Medicare (and many insurance plans) may deny payment for a service that is not reasonable and necessary according to the Medicare reimbursement rules. Thus, when a physician provides services to a Medicare beneficiary, he or she should only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient. A physician practice can bill in order to receive a denial for services, but only if the denial is needed for reimbursement from the secondary payor. Upon request, the physician practice should be able to provide documentation, such as a patient's medical records and

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[10] Physician practices seeking additional guidance on potential risk areas can review the OIG's Work Plan to identify vulnerabilities and risk areas on which the OIG will focus in the future. In addition, physician practices can also review the OIG's semiannual reports, which identify program vulnerabilities and risk areas that the OIG has targeted during the preceding six months. All of these documents are available on the OIG's webpage at http://www.hhs.gov/oig.

[11] Appendix A of this document lists additional risk areas that a physician practice may want to review and incorporate into their practice standards and procedures.

[12] For example, Dr. X, an ophthalmologist, billed for laser surgery he did not perform. As one element of proof, he did not even have laser equipment or access to such equipment at the place of service designated on the claim form where he performed the surgery.

[13] Billing for services, supplies and equipment that are not reasonable and necessary involves seeking reimbursement for a service that is not warranted by a patient's documented medical condition. See 42 U.S.C. 1395i(a)(1)(A) (''no payment may be made under part A or part B [of Medicare] for any expenses incurred for items or services which * * * are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member''). *See* also Appendix A for further discussion on this topic.

[14] Double billing occurs when a physician bills for the same item or service more than once or another party billed the Federal health care program for an item or service also billed by the physician. Although duplicate billing can occur due to simple error, the knowing submission of duplicate claims—which is sometimes evidenced by systematic or repeated double billing—can create liability under criminal, civil, and/or administrative law.

[15] For example, Dr. Y bills Medicare using a covered office visit code when the actual service was a non-covered annual physical. Physician practices should remember that ''necessary'' does not always constitute ''covered'' and that this example is a misrepresentation of services to the Federal health care programs.

[16] An example of this is when the practice bills for a service performed by Dr. B, who has not yet been issued a Medicare provider number, using Dr. A's Medicare provider number. Physician practices need to bill using the correct Medicare provider number, even if that means delaying billing until the physician receives his/her provider number.

[17] Unbundling is the practice of a physician billing for multiple components of a service that must be included in a single fee. For example, if dressings and instruments are included in a fee for a minor procedure, the provider may not also bill separately for the dressings and instruments.

[18] A modifier, as defined by the CPT–4 manual, provides the means by which a physician practice can indicate a service or procedure that has been performed has been altered by some specific circumstance, but not changed in its definition or code. Assuming the modifier is used correctly and appropriately, this specificity provides the justification for payment for those services. For correct use of modifiers, the physician practice should reference the appropriate sections of the *Medicare Provider Manual. See Medicare Carrier Manual* Section 4630. For general information on the correct use of modifiers, a physician practice can consult the National Correct Coding Initiative (NCCI). *See* Appendix F for information on how to download the NCCI edits. The NCCI coding edits are updated on a quarterly basis and are used to process claims and determine payments to physicians.

[19] This is the practice of coding/charging one or two middle levels of service codes exclusively, under the philosophy that some will be higher, some lower, and the charges will average out over an extended period (in reality, this overcharges some patients while undercharging others).

[20] Upcoding is billing for a more expensive service than the one actually performed. For example, Dr. X intentionally bills at a higher evaluation and management (E&M) code than what he actually renders to the patient.

[21] The official coding guidelines are promulgated by HCFA, the National Center for Health Statistics, the American Hospital Association, the American Medical Association and the American Health Information Management Association. *See* International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9 CM)(and its successors); 1998 Health Care Financing Administration Common Procedure Coding System (HCPCS) (and its successors); and Physicians' CPT. In addition, there are specialized coding systems for specific segments of the health care industry. Among these are ADA (for dental procedures), DSM IV (psychiatric health benefits) and DMERCs (for durable medical equipment, prosthetics, orthotics and supplies).

[22] The failure of a physician practice to: (i) document items and services rendered; and (ii) properly submit the corresponding claims for reimbursement is a major area of potential erroneous or fraudulent conduct involving Federal health care programs. The OIG has undertaken numerous audits, investigations, inspections and national enforcement initiatives in these areas.

[23] ''* * * for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' 42 U.S.C. 1395y(a)(1)(A).

physician's orders, to support the appropriateness of a service that the physician has provided.

c. Documentation. Timely, accurate and complete documentation is important to clinical patient care. This same documentation serves as a second function when a bill is submitted for payment, namely, as verification that the bill is accurate as submitted. Therefore, one of the most important physician practice compliance issues is the appropriate documentation of diagnosis and treatment. Physician documentation is necessary to determine the appropriate medical treatment for the patient and is the basis for coding and billing determinations. Thorough and accurate documentation also helps to ensure accurate recording and timely transmission of information.

i. Medical Record Documentation. In addition to facilitating high quality patient care, a properly documented medical record verifies and documents precisely what services were actually provided. The medical record may be used to validate: (a) The site of the service; (b) the appropriateness of the services provided; (c) the accuracy of the billing; and (d) the identity of the care giver (service provider). Examples of internal documentation guidelines a practice might use to ensure accurate medical record documentation include the following: [24]

- The medical record is complete and legible;
- The documentation of each patient encounter includes the reason for the encounter; any relevant history; physical examination findings; prior diagnostic test results; assessment, clinical impression, or diagnosis; plan of care; and date and legible identity of the observer;
- If not documented, the rationale for ordering diagnostic and other ancillary services can be easily inferred by an independent reviewer or third party who has appropriate medical training;
- CPT and ICD–9–CM codes used for claims submission are supported by documentation and the medical record; and
- Appropriate health risk factors are identified. The patient's progress, his or her response to, and any changes in, treatment, and any revision in diagnosis is documented.

The CPT and ICD–9–CM codes reported on the health insurance claims form should be supported by documentation in the medical record and the medical chart should contain all necessary information. Additionally, HCFA and the local carriers should be able to determine the person who provided the services. These issues can be the root of investigations of inappropriate or erroneous conduct, and have been identified by HCFA and the OIG as a leading cause of improper payments.

One method for improving quality in documentation is for a physician practice to compare the practice's claim denial rate to the rates of other practices in the same specialty to the extent that the practice can obtain that information from the carrier. Physician coding and diagnosis distribution can be compared for each physician within the same specialty to identify variances.

ii. HCFA 1500 Form. Another documentation area for physician practices to monitor closely is the proper completion of the HCFA 1500 form. The following practices will help ensure that the form has been properly completed:

- Link the diagnosis code with the reason for the visit or service;
- Use modifiers appropriately;
- Provide Medicare with all information about a beneficiary's other insurance coverage under the Medicare Secondary Payor (MSP) policy, if the practice is aware of a beneficiary's additional coverage.

d. Improper Inducements, Kickbacks and Self-Referrals. A physician practice would be well advised to have standards and procedures that encourage compliance with the anti-kickback statute [25] and the physician self-referral law.[26] Remuneration for referrals is illegal because it can distort medical decision-making, cause overutilization of services or supplies, increase costs to Federal health care programs, and result in unfair competition by shutting out competitors who are unwilling to pay for referrals. Remuneration for referrals can also affect the quality of patient care by encouraging physicians to order services or supplies based on profit rather than the patients' best medical interests.[27]

In particular, arrangements with hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers, pharmaceutical manufacturers and vendors are areas of potential concern. In general the anti-kickback statute prohibits knowingly and willfully giving or receiving anything of value to induce referrals of Federal health care program business. It is generally recommended that all business arrangements wherein physician practices refer business to, or order services or items from, an outside entity should be on a fair market value basis.[28] Whenever a physician practice intends to enter into a business arrangement that involves making referrals, the arrangement should be reviewed by legal counsel familiar with the anti-kickback statute and physician self-referral statute.

In addition to developing standards and procedures to address arrangements with other health care providers and suppliers, physician practices should also consider implementing measures to avoid offering inappropriate inducements to patients.[29] Examples of such inducements include routinely waiving coinsurance or deductible amounts without a good faith determination that the patient is in financial need or failing to make reasonable efforts to collect the cost-sharing amount.[30]

Possible risk factors relating to this risk area that could be addressed in the practice's standards and procedures include:

- Financial arrangements with outside entities to whom the practice

[24] For additional information on proper documentation, physician practices should also reference the *Documentation Guidelines for Evaluation and Management Services*, published by HCFA. Currently, physicians may document based on the 1995 or 1997 E&M Guidelines, whichever is most advantageous to the physician. A new set of draft guidelines were announced in June 2000, and are undergoing pilot testing and revision, but are not in current use.

[25] The anti-kickback statute provides criminal penalties for individuals and entities that knowingly offer, pay, solicit, or receive bribes or kickbacks or other remuneration in order to induce business reimbursable by Federal health care programs. *See* 42 U.S.C. 1320a–7b(b). Civil penalties, exclusion from participation in the Federal health care programs, and civil False Claims Act liability may also result from a violation of the prohibition. *See* 42 U.S.C. 1320a–7a(a)(5), 42 U.S.C. 1320a–7(b)(7), and 31 U.S.C. 3729–3733.

[26] The physician self-referral law, 42 U.S.C. 1395nn (also known as the ''Stark law''), prohibits a physician from making a referral to an entity with which the physician or any member of the physician's immediate family has a financial relationship if the referral is for the furnishing of designated health services, unless the financial relationship fits into an exception set forth in the statute or implementing regulations.

[27] *See* Appendix B for additional information on the anti-kickback statute.

[28] The OIG's definition of ''fair market value'' excludes any value attributable to referrals of Federal program business or the ability to influence the flow of such business. *See* 42 U.S.C. 1395nn(h)(3). Adhering to the rule of keeping business arrangements at fair market value is not a guarantee of legality, but is a highly useful general rule.

[29] *See* 42 U.S.C. 1320a–7a(a)(5).

[30] In the OIG Special Fraud Alert ''Routine Waiver of Part B Co-payments/Deductibles'' (May 1991), the OIG describes several reasons why routine waivers of these cost-sharing amounts pose concerns. The Alert sets forth the circumstances under which it may be appropriate to waive these amounts. *See* also 42 U.S.C. 1320a–7a(a)(5).

may refer Federal health care program business;[31]

• Joint ventures with entities supplying goods or services to the physician practice or its patients;[32]

• Consulting contracts or medical directorships;

• Office and equipment leases with entities to which the physician refers; and

• Soliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician practice's referral of Federal health care program business.[33]

In order to keep current with this area of the law, a physician practice may obtain copies, available on the OIG web site or in hard copy from the OIG, of all relevant OIG Special Fraud Alerts and Advisory Opinions that address the application of the anti-kickback and physician self-referral laws to ensure that the standards and procedures reflect current positions and opinions.

2. Retention of Records

In light of the documentation requirements faced by physician practices, it would be to the practice's benefit if its standards and procedures contained a section on the retention of compliance, business and medical records. These records primarily include documents relating to patient care and the practice's business activities. A physician practice's designated compliance contact could keep an updated binder or record of these documents, including information relating to compliance activities. The primary compliance documents that a practice would want to retain are those that relate to educational activities, internal investigations and internal audit results. We suggest that particular attention should be paid to documenting investigations of potential violations uncovered by the compliance program and the resulting remedial action. Although there is no requirement that the practice retain its compliance records, having all the relevant documentation relating to the practice's compliance efforts or handling of a particular problem can benefit the practice should it ever be questioned regarding those activities.

Physician practices that implement a compliance program might also want to provide for the development and implementation of a records retention system. This system would establish standards and procedures regarding the creation, distribution, retention, and destruction of documents. If the practice decides to design a record system, privacy concerns and Federal or State regulatory requirements should be taken into consideration.[34]

While conducting its compliance activities, as well as its daily operations, a physician practice would be well advised, to the extent it is possible, to document its efforts to comply with applicable Federal health care program requirements. For example, if a physician practice requests advice from a Government agency (including a Medicare carrier) charged with administering a Federal health care program, it is to the benefit of the practice to document and retain a record of the request and any written or oral response (or nonresponse). This step is extremely important if the practice intends to rely on that response to guide it in future decisions, actions, or claim reimbursement requests or appeals.

In short, it is in the best interest of all physician practices, regardless of size, to have procedures to create and retain appropriate documentation. The following record retention guidelines are suggested:

• The length of time that a practice's records are to be retained can be specified in the physician practice's standards and procedures (Federal and State statutes should be consulted for specific time frames, if applicable);

• Medical records (if in the possession of the physician practice) need to be secured against loss, destruction, unauthorized access, unauthorized reproduction, corruption, or damage; and

• Standards and procedures can stipulate the disposition of medical records in the event the practice is sold or closed.

Step Three: Designation of a Compliance Officer/Contact(s)

After the audits have been completed and the risk areas identified, ideally one member of the physician practice staff needs to accept the responsibility of developing a corrective action plan, if necessary, and oversee the practice's adherence to that plan. This person can either be in charge of all compliance activities for the practice or play a limited role merely to resolve the current issue. In a formalized institutional compliance program there is a compliance officer who is responsible for overseeing the implementation and day-to-day operations of the compliance program. However, the resource constraints of physician practices make it so that it is often impossible to designate one person to be in charge of compliance functions.

It is acceptable for a physician practice to designate more than one employee with compliance monitoring responsibility. In lieu of having a designated compliance officer, the physician practice could instead describe in its standards and procedures the compliance functions for which designated employees, known as ''compliance contacts,'' would be responsible. For example, one employee could be responsible for preparing written standards and procedures, while another could be responsible for conducting or arranging for periodic audits and ensuring that billing questions are answered. Therefore, the compliance-related responsibilities of the designated person or persons may be only a portion of his or her duties.

Another possibility is that one individual could serve as compliance officer for more than one entity. In situations where staffing limitations mandate that the practice cannot afford to designate a person(s) to oversee compliance activities, the practice could outsource all or part of the functions of a compliance officer to a third party, such as a consultant, PPMC, MSO, IPA or third-party billing company. However, if this role is outsourced, it is beneficial for the compliance officer to have sufficient interaction with the physician practice to be able to effectively understand the inner workings of the practice. For example, consultants that are not in close geographic proximity to a practice may not be effective compliance officers for the practice.

[31] All physician contracts and agreements with parties in a position to influence Federal health care program business or to whom the doctor is in such a position to influence should be reviewed to avoid violation of the anti-kickback, self-referral, and other relevant Federal and State laws. The OIG has published safe harbors that define practices not subject to the anti-kickback statute, because such arrangements would be unlikely to result in fraud or abuse. Failure to comply with a safe harbor provision does not make an arrangement per se illegal. Rather, the safe harbors set forth specific conditions that, if fully met, would assure the entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. One such safe harbor applies to personal services contracts. *See* 42 CFR 1001.952(d).

[32] *See* OIG Special Fraud Alert ''Joint Venture Arrangements'' (August 1989) available on the OIG web site at http://www.hhs.gov/oig. *See also* OIG Advisory Opinion 97–5.

[33] Physician practices should establish clear standards and procedures governing gift-giving because such exchanges may be viewed as inducements to influence business decisions.

[34] There are various Federal regulations governing the privacy of patient records and the retention of certain types of patient records. Many states also have record retention statutes. Practices should check with their state medical society and/or affiliated professional association for assistance in ascertaining these requirements for their particular specialty and location.

One suggestion for how to maintain continual interaction is for the practice to designate someone to serve as a liaison with the outsourced compliance officer. This would help ensure a strong tie between the compliance officer and the practice's daily operations. Outsourced compliance officers, who spend most of their time offsite, have certain limitations that a physician practice should consider before making such a critical decision. These limitations can include lack of understanding as to the inner workings of the practice, accessibility and possible conflicts of interest when one compliance officer is serving several practices.

If the physician practice decides to designate a particular person(s) to oversee all compliance activities, not just those in conjunction with the audit-related issue, the following is a list of suggested duties that the practice may want to assign to that person(s):

- Overseeing and monitoring the implementation of the compliance program;
- Establishing methods, such as periodic audits, to improve the practice's efficiency and quality of services, and to reduce the practice's vulnerability to fraud and abuse;
- Periodically revising the compliance program in light of changes in the needs of the practice or changes in the law and in the standards and procedures of Government and private payor health plans;
- Developing, coordinating and participating in a training program that focuses on the components of the compliance program, and seeks to ensure that training materials are appropriate;
- Ensuring that the HHS–OIG's List of Excluded Individuals and Entities, and the General Services Administration's (GSA's) List of Parties Debarred from Federal Programs have been checked with respect to all employees, medical staff and independent contractors; [35] and
- Investigating any report or allegation concerning possible unethical or improper business practices, and monitoring subsequent corrective action and/or compliance.

Each physician practice needs to assess its own practice situation and determine what best suits that practice in terms of compliance oversight.

Step Four: Conducting Appropriate Training and Education

Education is an important part of any compliance program and is the logical next step after problems have been identified and the practice has designated a person to oversee educational training. Ideally, education programs will be tailored to the physician practice's needs, specialty and size and will include both compliance and specific training.

There are three basic steps for setting up educational objectives:

- Determining who needs training (both in coding and billing and in compliance);
- Determining the type of training that best suits the practice's needs (*e.g.*, seminars, in-service training, self-study or other programs); and
- Determining when and how often education is needed and how much each person should receive.

Training may be accomplished through a variety of means, including in-person training sessions (*i.e.*, either on site or at outside seminars), distribution of newsletters,[36] or even a readily accessible office bulletin board. Regardless of the training modality used, a physician practice should ensure that the necessary education is communicated effectively and that the practice's employees come away from the training with a better understanding of the issues covered.

1. Compliance Training

Under the direction of the designated compliance officer/contact, both initial and recurrent training in compliance is advisable, both with respect to the compliance program itself and applicable statutes and regulations. Suggestions for items to include in compliance training are: The operation and importance of the compliance program; the consequences of violating the standards and procedures set forth in the program; and the role of each employee in the operation of the compliance program.

There are two goals a practice should strive for when conducting compliance training: (1) All employees will receive training on how to perform their jobs in compliance with the standards of the practice and any applicable regulations; and (2) each employee will understand that compliance is a condition of continued employment. Compliance training focuses on explaining why the practice is developing and establishing a compliance program. The training should emphasize that following the standards and procedures will not get a practice employee in trouble, but violating the standards and procedures may subject the employee to disciplinary measures. It is advisable that new employees be trained on the compliance program as soon as possible after their start date and employees should receive refresher training on an annual basis or as appropriate.

2. Coding and Billing Training

Coding and billing training on the Federal health care program requirements may be necessary for certain members of the physician practice staff depending on their respective responsibilities. The OIG understands that most physician practices do not employ a professional coder and that the physician is often primarily responsible for all coding and billing. However, it is in the practice's best interest to ensure that individuals who are directly involved with billing, coding or other aspects of the Federal health care programs receive extensive education specific to that individual's responsibilities. Some examples of items that could be covered in coding and billing training include:

- Coding requirements;
- Claim development and submission processes;
- Signing a form for a physician without the physician's authorization;
- Proper documentation of services rendered;
- Proper billing standards and procedures and submission of accurate bills for services or items rendered to Federal health care program beneficiaries; and
- The legal sanctions for submitting deliberately false or reckless billings.

3. Format of the Training Program

Training may be conducted either in-house or by an outside source.[37]

[35] The HHS–OIG ''List of Excluded Individuals/Entities'' provides information to health care providers, patients, and others regarding individuals and entities that are excluded from participation in Federal health care programs. This report, in both an on-line searchable and downloadable database, can be located on the Internet at http://www.hhs.gov/oig. The OIG sanction information is readily available to users in two formats on over 15,000 individuals and entities currently excluded from program participation through action taken by the OIG. The on-line searchable database allows users to obtain information regarding excluded individuals and entities sorted by: (1) The legal bases for exclusions; (2) the types of individuals and entities excluded by the OIG; and (3) the States where excluded individuals reside or entities do business. In addition, the General Services Administration maintains a monthly listing of debarred contractors, ''List of Parties Debarred from Federal Programs,'' at http://www.arnet.gov/epls.

[36] HCFA also offers free online training for general fraud and abuse issues at *http://www.hcfa.gov/medlearn. See* Appendix F for additional information.

[37] As noted earlier in this guidance, another way for physician practices to receive training is for the physicians and/or the employees of the practice to attend training programs offered by outside entities, such as a hospital, a local medical society or a

Training at outside seminars, instead of internal programs and in-service sessions, may be an effective way to achieve the practice's training goals. In fact, many community colleges offer certificate or associate degree programs in billing and coding, and professional associations provide various kinds of continuing education and certification programs. Many carriers also offer billing training.

The physician practice may work with its third-party billing company, if one is used, to ensure that documentation is of a level that is adequate for the billing company to submit accurate claims on behalf of the physician practice. If it is not, these problem areas should also be covered in the training. In addition to the billing training, it is advisable for physician practices to maintain updated ICD–9, HCPCS and CPT manuals (in addition to the carrier bulletins construing those sources) and make them available to all employees involved in the billing process. Physician practices can also provide a source of continuous updates on current billing standards and procedures by making publications or Government documents that describe current billing policies available to its employees.[38]

Physician practices do not have to provide separate education and training programs for the compliance and coding and billing training. All in-service training and continuing education can integrate compliance issues, as well as other core values adopted by the practice, such as quality improvement and improved patient service, into their curriculum.

4. Continuing Education on Compliance Issues

There is no set formula for determining how often training sessions should occur. The OIG recommends that there be at least an annual training program for all individuals involved in the coding and billing aspects of the practice.[39] Ideally, new billing and coding employees will be trained as soon as possible after assuming their duties and will work under an experienced employee until their training has been completed.

Step Five: Responding To Detected Offenses and Developing Corrective Action Initiatives

When a practice determines it has detected a possible violation, the next step is to develop a corrective action plan and determine how to respond to the problem. Violations of a physician practice's compliance program, significant failures to comply with applicable Federal or State law, and other types of misconduct threaten a practice's status as a reliable, honest, and trustworthy provider of health care. Consequently, upon receipt of reports or reasonable indications of suspected noncompliance, it is important that the compliance contact or other practice employee look into the allegations to determine whether a significant violation of applicable law or the requirements of the compliance program has indeed occurred, and, if so, take decisive steps to correct the problem.[40] As appropriate, such steps may involve a corrective action plan,[41] the return of any overpayments, a report to the Government,[42] and/or a referral to law enforcement authorities.

One suggestion is that the practice, in developing its compliance program, develop its own set of monitors and warning indicators. These might include: Significant changes in the number and/or types of claim rejections and/or reductions; correspondence from the carriers and insurers challenging the medical necessity or validity of claims; illogical patterns or unusual changes in the pattern of CPT–4, HCPCS or ICD–9 code utilization; and high volumes of unusual charge or payment adjustment transactions. If any of these warning indicators become apparent, then it is recommended that the practice follow up on the issues. Subsequently, as appropriate, the compliance procedures of the practice may need to be changed to prevent the problem from recurring.

For potential criminal violations, a physician practice would be well advised in its compliance program procedures to include steps for prompt referral or disclosure to an appropriate Government authority or law enforcement agency. In regard to overpayment issues, it is advised that the physician practice take appropriate corrective action, including prompt identification and repayment of any overpayment to the affected payor.

It is also recommended that the compliance program provide for a full internal assessment of all reports of detected violations. If the physician practice ignores reports of possible fraudulent activity, it is undermining the very purpose it hoped to achieve by implementing a compliance program.

It is advised that the compliance program standards and procedures include provisions to ensure that a violation is not compounded once discovered. In instances involving individual misconduct, the standards and procedures might also advise as to whether the individuals involved in the violation either be retrained, disciplined, or, if appropriate, terminated. The physician practice may also prevent the compounding of the violation by conducting a review of all confirmed violations, and, if appropriate, self-reporting the violations to the applicable authority.

The physician practice may consider the fact that if a violation occurred and was not detected, its compliance program may require modification. Physician practices that detect violations could analyze the situation to determine whether a flaw in their compliance program failed to anticipate the detected problem, or whether the compliance program's procedures failed to prevent the violation. In any event, it is prudent, even absent the detection of any violations, for physician practices to periodically review and modify their compliance programs.

Step Six: Developing Open Lines of Communication

In order to prevent problems from occurring and to have a frank discussion

carrier. This sort of collaborative effort is an excellent way for the practice to meet the desired training objective without having to expend the resources to develop and implement in-house training.

[38] Some publications, such as OIG's Special Fraud Alerts, audit and inspection reports, and Advisory Opinions are readily available from the OIG and can provide a basis for educational courses and programs for physician practice employees. *See* Appendix F for a partial listing of these documents. *See* Footnote 3 for information on how to obtain copies of these documents.

[39] Currently, the OIG is monitoring a significant number of corporate integrity agreements that require many of these training elements. The OIG usually requires a minimum of one hour annually for basic training in compliance areas. Additional training may be necessary for specialty fields such as claims development and billing.

[40] Instances of noncompliance must be determined on a case-by-case basis. The existence or amount of a monetary loss to a health care program is not solely determinative of whether the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss to a health care provider, but corrective actions are still necessary to protect the integrity of the applicable program and its beneficiaries, *e.g.,* where services required by a plan of care are not provided.

[41] The physician practice may seek advice from its legal counsel to determine the extent of the practice's liability and to plan the appropriate course of action.

[42] The OIG has established a Provider Self-Disclosure Protocol that encourages providers to voluntarily report suspected fraud. The concept of voluntary self-disclosure is premised on a recognition that the Government alone cannot protect the integrity of the Medicare and other Federal health care programs. Health care providers must be willing to police themselves, correct underlying problems, and work with the Government to resolve these matters. The Provider Self-Disclosure Protocol can be located on the OIG's web site at: www.hhs.gov/oig. *See* Appendix D for further information on the Provider Self-Disclosure Protocol.

of why the problem happened in the first place, physician practices need to have open lines of communication. Especially in a smaller practice, an open line of communication is an integral part of implementing a compliance program. Guidance previously issued by the OIG has encouraged the use of several forms of communication between the compliance officer/committee and provider personnel, many of which focus on formal processes and are more costly to implement (*e.g.,* hotlines and e-mail). However, the OIG recognizes that the nature of some physician practices is not as conducive to implementing these types of measures. The nature of a small physician practice dictates that such communication and information exchanges need to be conducted through a less formalized process than that which has been envisioned by prior OIG guidance.

In the small physician practice setting, the communication element may be met by implementing a clear ''open door'' policy between the physicians and compliance personnel and practice employees. This policy can be implemented in conjunction with less formal communication techniques, such as conspicuous notices posted in common areas and/or the development and placement of a compliance bulletin board where everyone in the practice can receive up-to-date compliance information.[43]

A compliance program's system for meaningful and open communication can include the following:

- The requirement that employees report conduct that a reasonable person would, in good faith, believe to be erroneous or fraudulent;
- The creation of a user-friendly process (such as an anonymous drop box for larger practices) for effectively reporting erroneous or fraudulent conduct;
- Provisions in the standards and procedures that state that a failure to report erroneous or fraudulent conduct is a violation of the compliance program;
- The development of a simple and readily accessible procedure to process reports of erroneous or fraudulent conduct;
- If a billing company is used, communication to and from the billing company's compliance officer/contact and other responsible staff to coordinate billing and compliance activities of the practice and the billing company, respectively. Communication can include, as appropriate, lists of reported or identified concerns, initiation and the results of internal assessments, training needs, regulatory changes, and other operational and compliance matters;
- The utilization of a process that maintains the anonymity of the persons involved in the reported possible erroneous or fraudulent conduct and the person reporting the concern; and
- Provisions in the standards and procedures that there will be no retribution for reporting conduct that a reasonable person acting in good faith would have believed to be erroneous or fraudulent.

The OIG recognizes that protecting anonymity may not be feasible for small physician practices. However, the OIG believes all practice employees, when seeking answers to questions or reporting potential instances of erroneous or fraudulent conduct, should know to whom to turn for assistance in these matters and should be able to do so without fear of retribution. While the physician practice may strive to maintain the anonymity of an employee's identity, it also needs to make clear that there may be a point at which the individual's identity may become known or may have to be revealed in certain instances.

Step Seven: Enforcing Disciplinary Standards Through Well-Publicized Guidelines

Finally, the last step that a physician practice may wish to take is to incorporate measures into its practice to ensure that practice employees understand the consequences if they behave in a non-compliant manner. An effective physician practice compliance program includes procedures for enforcing and disciplining individuals who violate the practice's compliance or other practice standards. Enforcement and disciplinary provisions are necessary to add credibility and integrity to a compliance program.

The OIG recommends that a physician practice's enforcement and disciplinary mechanisms ensure that violations of the practice's compliance policies will result in consistent and appropriate sanctions, including the possibility of termination, against the offending individual. At the same time, it is advisable that the practice's enforcement and disciplinary procedures be flexible enough to account for mitigating or aggravating circumstances. The procedures might also stipulate that individuals who fail to detect or report violations of the compliance program may also be subject to discipline. Disciplinary actions could include: Warnings (oral); reprimands (written); probation; demotion; temporary suspension; termination; restitution of damages; and referral for criminal prosecution. Inclusion of disciplinary guidelines in in-house training and procedure manuals is sufficient to meet the ''well publicized'' standard of this element.

It is suggested that any communication resulting in the finding of non-compliant conduct be documented in the compliance files by including the date of incident, name of the reporting party, name of the person responsible for taking action, and the follow-up action taken. Another suggestion is for physician practices to conduct checks to make sure all current and potential practice employees are not listed on the OIG or GSA lists of individuals excluded from participation in Federal health care or Government procurement programs.[44]

C. Assessing A Voluntary Compliance Program

A practice's commitment to compliance can best be assessed by the active application of compliance principles in the day-to-day operations of the practice. Compliance programs are not just written standards and procedures that sit on a shelf in the main office of a practice, but are an everyday part of the practice operations. It is by integrating the compliance program into the practice culture that the practice can best achieve maximum benefit from its compliance program.

III. Conclusion

Just as immunizations are given to patients to prevent them from becoming ill, physician practices may view the implementation of a voluntary compliance program as comparable to a form of preventive medicine for the practice. This voluntary compliance program guidance is intended to assist physician practices in developing and implementing internal controls and procedures that promote adherence to Federal health care program requirements.

As stated earlier, physician compliance programs do not need to be time or resource intensive and can be developed in a manner that best reflects the nature of each individual practice. Many of the recommendations set forth in this document are ones that many physician practices already have in place and are simply good business practices that can be adhered to with a

[43] In addition to whatever other method of communication is being utilized, the OIG recommends that physician practices post the HHS–OIG Hotline telephone number (1–800–HHS–TIPS) in a prominent area.

[44] *See* Footnote 35 for information on how to access these lists.

reasonable amount of effort. By implementing an effective compliance program, appropriate for its size and resources, and making compliance principles an active part of the practice culture, a physician practice can help prevent and reduce erroneous or fraudulent conduct in its practice. These efforts can also streamline and improve the business operations within the practice and therefore innoculate itself against future problems.

Dated: September 27, 2000.

June Gibbs Brown,

Inspector General.

Appendix A: Additional Risk Areas

Appendix A describes additional risk areas that a physician practice may wish to address during the development of its compliance program. If any of the following risk areas are applicable to the practice, the practice may want to consider addressing the risk areas by incorporating them into the practice's written standards and procedures manual and addressing them in its training program.

I. Reasonable and Necessary Services

A. Local Medical Review Policy

An area of concern for physicians relating to determinations of reasonable and necessary services is the variation in local medical review policies (LMRPs) among carriers. Physicians are supposed to bill the Federal health care programs only for items and services that are reasonable and necessary. However, in order to determine whether an item or service is reasonable and necessary under Medicare guidelines, the physician must apply the appropriate LMRP.[1]

With the exception of claims that are properly coded and submitted to Medicare solely for the purpose of obtaining a written denial, physician practices are to bill the Federal health programs only for items and services that are covered. In order to determine if an item or service is covered for Medicare, a physician practice must be knowledgeable of the LMRPs applicable to its practice's jurisdiction. The practice may contact its carrier to request a copy of the pertinent LMRPs, and once the practice receives the copies, they can be incorporated into the practice's written standards and procedures manual. When the LMRP indicates that an item or service may not be covered by Medicare, the physician practice is responsible to convey this information to the patient so that the patient can make an informed decision concerning the health care services he/she may want to receive. Physician practices convey this information through Advance Beneficiary Notices (ABNs).

[1] HCFA has recently developed a web site which, when completed by the end of the year 2000, will contain the LMRPs for each of the contractors across the country. The web site can be accessed at http://www.lmrp.net.

B. Advance Beneficiary Notices

Physicians are required to provide ABNs before they provide services that they know or believe Medicare does not consider reasonable and necessary. (The one exception to this requirement is for services that are performed pursuant to EMTALA requirements as described in section II.A). A properly executed ABN acknowledges that coverage is uncertain or yet to be determined, and stipulates that the patient promises to pay the bill if Medicare does not. Patients who are not notified before they receive such services are not responsible for payment. The ABN must be sufficient to put the patient on notice of the reasons why the physician believes that the payment may be denied. The objective is to give the patient sufficient information to allow an informed choice as to whether to pay for the service.

Accordingly, each ABN should:

I. Be in writing;
II. Identify the specific service that may be denied (procedure name and CPT/HCPC code is recommended);
III. State the specific reason why the physician believes that service may be denied; and
IV. Be signed by the patient acknowledging that the required information was provided and that the patient assumes responsibility to pay for the service.

The Medicare Carrier's Manual [2] provides that an ABN will not be acceptable if: (1) The patient is asked to sign a blank ABN form; or (2) the ABN is used routinely without regard to a particularized need. The routine use of ABNs is generally prohibited because the ABN must state the specific reason the physician anticipates that the specific service will not be covered.

A common risk area associated with ABNs is in regard to diagnostic tests or services. There are three steps that a physician practice can take to help ensure it is in compliance with the regulations concerning ABNs for diagnostic tests or services:

1. Determine which tests are not covered under national coverage rules;
2. Determine which tests are not covered under local coverage rules such as LMRPs (contact the practice's carrier to see if a listing has been assembled); and
3. Determine which tests are only covered for certain diagnoses.

The OIG is aware that the use of ABNs is an area where physician practices experience numerous difficulties. Practices can help to reduce problems in this area by educating their physicians and office staff on the correct use of ABNs, obtaining guidance from the carrier regarding their interpretation of whether an ABN is necessary where the service is not covered, developing a standard form for all diagnostic tests (most carriers have a developed model), and developing a process for handling patients who refuse to sign ABNs.

[2] The relevant manual provisions are located at MCM, Part III, §§ 7300 and 7320. This section of the manual also includes the carrier's recommended form of an ABN.

C. Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services

In January 1999, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at *www.hhs.gov/oig/frdalrt/index.htm.* The following is a summary of the Special Fraud Alert.

The OIG issued the Special Fraud Alert to reiterate to physicians the legal and programmatic significance of physician certifications made in connection with the ordering of certain items and services for Medicare patients. In light of information obtained through OIG provider audits, the OIG deemed it necessary to remind physicians that they may be subject to criminal, civil and administrative penalties for signing a certification when they know that the information is false or for signing a certification with reckless disregard as to the truth of the information. (*See Appendix B* and *Appendix C* for more detailed information on the applicable statutes).

Medicare has conditioned payment for many items and services on a certification signed by a physician attesting that the physician has reviewed the patient's condition and has determined that an item or service is reasonable and necessary. Because Medicare primarily relies on the professional judgment of the treating physician to determine the reasonable and necessary nature of a given service or supply, it is important that physicians provide complete and accurate information on any certifications they sign. Physician certification is obtained through a variety of forms, including prescriptions, orders, and Certificates of Medical Necessity (CMNs). Two areas where physician certification as to whether an item or service is reasonable and necessary is essential and which are vulnerable to abuse are: (1) Home health services; and (2) durable medical equipment.

By signing a CMN, the physician represents that:

1. He or she is the patient's treating physician and that the information regarding the physician's address and unique physician identification number (UPIN) is correct;
2. the entire CMN, including the sections filled out by the supplier, was completed *prior* to the physician's signature; and
3. the information in section B relating to whether the item or service is reasonable and necessary is true, accurate, and complete to the best of the physician's knowledge.

Activities such as signing blank CMNs, signing a CMN without seeing the patient to verify the item or service is reasonable and necessary, and signing a CMN for a service that the physician knows is not reasonable and necessary are activities that can lead to criminal, civil and administrative penalties.

Ultimately, it is advised that physicians carefully review any form of certification (order, prescription or CMN) before signing it to verify that the information contained in the certification is both complete and accurate.

D. Billing for Non-covered Services as if Covered

In some instances, we are aware that physician practices submit claims for services in order to receive a denial from the carrier, thereby enabling the patient to submit the denied claim for payment to a secondary payer.

A common question relating to this risk area is: If the medical services provided are not covered under Medicare, but the secondary or supplemental insurer requires a Medicare rejection in order to cover the services, then would the original submission of the claim to Medicare be considered fraudulent? Under the applicable regulations, the OIG would not consider such submissions to be fraudulent. For example, the denial may be necessary to establish patient liability protections as stated in section 1879 of the Social Security Act (the Act) (codified at 42 U.S.C. 1395pp). As stated, Medicare denials may also be required so that the patient can seek payment from a secondary insurer. In instances where a claim is being submitted to Medicare for this purpose, the physician should indicate on the claim submission that the claim is being submitted for the purpose of receiving a denial, in order to bill a secondary insurance carrier. This step should assist carriers and prevent inadvertent payments to which the physician is not entitled.

In some instances, however, the carrier pays the claim even though the service is non-covered, and even though the physician did not intend for payment to be made. When this occurs, the physician has a responsibility to refund the amount paid and indicate that the service is not covered.

II. Physician Relationships with Hospitals

A. The Physician Role in EMTALA

The Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. 1395dd, is an area that has been receiving increasing scrutiny. The statute is intended to ensure that all patients who come to the emergency department of a hospital receive care, regardless of their insurance or ability to pay. Both hospitals and physicians need to work together to ensure compliance with the provisions of this law.

The statute imposes three fundamental requirements upon hospitals that participate in the Medicare program with regard to patients requesting emergency care. First, the hospital must conduct an appropriate medical screening examination to determine if an emergency medical condition exists.[3] Second, if the hospital determines that an emergency medical condition exists, it must either provide the treatment necessary to stabilize the emergency medical condition or comply with the statute's requirements to effect a proper transfer of a patient whose condition has not been stabilized.[4] A hospital is considered to have met this second requirement if an individual refuses the hospital's offer of additional examination or treatment, or refuses to consent to a transfer, after having been informed of the risks and benefits.[5]

If an individual's emergency medical condition has not been stabilized, the statute's third requirement is activated. A hospital may not transfer an individual with an unstable emergency medical condition unless: (1) The individual or his or her representative makes a written request for transfer to another medical facility after being informed of the risk of transfer and the transferring hospital's obligation under the statute to provide additional examination or treatment; (2) a physician has signed a certification summarizing the medical risks and benefits of a transfer and certifying that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the transfer outweigh the increased risks; or (3) if a physician is not physically present when the transfer decision is made, a qualified medical person signs the certification after the physician, in consultation with the qualified medical person, has made the determination that the benefits of transfer outweigh the increased risks. The physician must later countersign the certification.[6]

Physician and/or hospital misconduct may result in violations of the statute.[7] One area of particular concern is physician on-call responsibilities. Physician practices whose members serve as on-call emergency room physicians with hospitals are advised to familiarize themselves with the hospital's policies regarding on-call physicians. This can be done by reviewing the medical staff bylaws or policies and procedures of the hospital that must define the responsibility of on-call physicians to respond to, examine, and treat patients with emergency medical conditions. Physicians should also be aware of the requirement that, when medically indicated, on-call physicians must generally come to the hospital to examine the patient. The exception to this requirement is that a patient may be sent to see the on-call physician at a hospital-owned contiguous or on-campus facility to conduct or complete the medical screening examination as long as:

1. All persons with the same medical condition are moved to this location;
2. there is a bona fide medical reason to move the patient; and
3. qualified medical personnel accompany the patient.

B. Teaching Physicians

Special regulations apply to teaching physicians' billings. Regulations provide that services provided by teaching physicians in teaching settings are generally payable under the physician fee schedule only if the services are personally furnished by a physician who is not a resident or the services are furnished by a resident in the presence of a teaching physician.[8]

Unless a service falls under a specified exception, such as the Primary Care Exception,[9] the teaching physician must be present during the key portion of any service or procedure for which payment is sought.[10] Physicians should ensure the following with respect to services provided in the teaching physician setting [11]

- Only services actually provided are billed;
- Every physician who provides or supervises the provision of services to a patient is responsible for the correct documentation of the services that were rendered;
- Every physician is responsible for assuring that in cases where the physician provides evaluation and management (E&M) services, a patient's medical record includes appropriate documentation of the applicable key components of the E&M services provided or supervised by the physician (*e.g.,* patient history, physician examination, and medical decision making), as well as documentation to adequately reflect the procedure or portion of the services provided by the physician; and
- Unless specifically excepted by regulation, every physician must document his or her presence during the key portion of any service or procedure for which payment is sought.

C. Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

In July 1999, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at *www.hhs.gov/oig/frdalrt/index.htm.* The following is a summary of the Special Fraud Alert.

The term ''gainsharing'' typically refers to an arrangement in which a hospital gives a physician a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physician's efforts. The civil monetary penalty (CMP) that applies to gainsharing arrangements is set forth in 42 U.S.C. 1320a–7a(b)(1). This section prohibits any hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under a physician's care.

It is the OIG's position that the Civil Monetary Penalties Law clearly prohibits any gainsharing arrangements that involve payments by, or on behalf of, a hospital to physicians with clinical care responsibilities to induce a reduction or limitation of services to Medicare or Medicaid beneficiaries. However, hospitals and physicians are not prohibited from working together to reduce unnecessary hospital costs through other

[3] *See* 42 U.S.C. 1395dd(a).

[4] *See* 42 U.S.C. 1395dd(b)(1).

[5] *See* 42 U.S.C. 1395dd(b)(2) and (3).

[6] *See* 42 U.S.C. 1395dd(c)(1)(A).

[7] Hospitals and physicians, including on-call physicians, who violate the statute may face penalties that include civil fines of up to $50,000 (or not more than $25,000 in the case of a hospital with less than 100 beds) per violation, and physicians may be excluded from participation in the Federal health care programs.

[8] 42 CFR 415.150 through 415.190.

[9] 42 CFR 415.174.

[10] *Id.*

[11] This section is not intended to be and is not a complete reference for teaching physicians. It is strongly recommended that those physicians who practice in a teaching setting consult their respective hospitals for more guidance.

arrangements. For example, hospitals and physicians may enter into personal services contracts where hospitals pay physicians based on a fixed fee at fair market value for services rendered to reduce costs rather than a fee based on a share of cost savings.

D. Physician Incentive Arrangements

The OIG has identified potentially illegal practices involving the offering of incentives by entities in an effort to recruit and retain physicians. The OIG is concerned that the intent behind offering incentives to physicians may not be to recruit physicians, but instead the offer is intended as a kickback to obtain and increase patient referrals from physicians. These recruitment incentive arrangements are implicated by the Anti-Kickback Statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid.

Some examples of questionable incentive arrangements are:

- Provision of free or significantly discounted billing, nursing, or other staff services.
- Payment of the cost of a physician's travel and expenses for conferences.
- Payment for a physician's services that require few, if any, substantive duties by the physician.
- Guarantees that if the physician's income fails to reach a predetermined level, the entity will supplement the remainder up to a certain amount.

III. Physician Billing Practices

A. Third-Party Billing Services

Physicians should remember that they remain responsible to the Medicare program for bills sent in the physician's name or containing the physician's signature, even if the physician had no actual knowledge of a billing impropriety. The attestation on the HCFA 1500 form, *i.e.,* the physician's signature line, states that the physician's services were billed properly. In other words, it is no defense for the physician if the physician's billing service improperly bills Medicare.

One of the most common risk areas involving billing services deals with physician practices contracting with billing services on a percentage basis. Although percentage based billing arrangements are not illegal *per se,* the Office of Inspector General has a longstanding concern that such arrangements may increase the risk of intentional upcoding and similar abusive billing practices.[12]

A physician may contract with a billing service on a percentage basis. However, the billing service cannot directly receive the payment of Medicare funds into a bank account that it solely controls. Under 42 U.S.C. 1395u(b)(6), Medicare payments can only be made to either the beneficiary or a party (such as a physician) that furnished the services and accepted assignment of the beneficiary's claim. A billing service that contracts on a percentage basis does not qualify as a party that furnished services to a beneficiary, thus a billing service cannot directly receive payment of Medicare funds. According to the *Medicare Carriers Manual* Section 3060(A), a payment is considered to be made directly to the billing service if the service can convert the payment to its own use and control without the payment first passing through the control of the physician. For example, the billing service should not bill the claims under its own name or tax identification number. The billing service should bill claims under the physician's name and tax identification number. Nor should a billing service receive the payment of Medicare funds directly into a bank account over which the billing service maintains sole control. The Medicare payments should instead be deposited into a bank account over which the provider has signature control.

Physician practices should review the third-party medical billing guidance for additional information on third-party billing companies and the compliance risk areas associated with billing companies.

B. Billing Practices by Non-Participating Physicians

Even though nonparticipating physicians do not accept payment directly from the Medicare program, there are a number of laws that apply to the billing of Medicare beneficiaries by non-participating physicians.

Limiting Charges

42 U.S.C. 1395w–4(g) prohibits a nonparticipating physician from knowingly and willfully billing or collecting on a repeated basis an actual charge for a service that is in excess of the Medicare limiting charge. For example, a nonparticipating physician may not bill a Medicare beneficiary $50 for an office visit when the Medicare limiting charge for the visit is $25. Additionally, there are numerous provisions that prohibit nonparticipating physicians from knowingly and willfully charging patients in excess of the statutory charge limitations for certain specified procedures, such as cataract surgery, mammography screening and coronary artery bypass surgery. Failure to comply with these sections can result in a fine of up to $10,000 per violation or exclusion from participation in Federal health care programs for up to 5 years.

Refund of Excess Charges

42 U.S.C. 1395w–4(g) mandates that if a nonparticipating physician collects an actual charge for a service that is in excess of the limiting charge, the physician must refund the amount collected above the limiting charge to the individual within 30 days notice of the violation. For example, if a physician collected $50 from a Medicare beneficiary for an office visit, but the limiting charge for the visit was $25, the physician must refund $25 to the beneficiary, which is the difference between the amount collected ($50) and the limiting charge ($25). Failure to comply with this requirement may result in a fine of up to $10,000 per violation or exclusion from participation in Federal health care programs for up to 5 years.

Specifically, 42 U.S.C. 1395u(l)(A)(iii) mandates that a nonparticipating physician must refund payments received from a Medicare beneficiary if it is later determined by a Peer Review Organization or a Medicare carrier that the services were not reasonable and necessary. Failure to comply with this requirement may result in a fine of up to $10,000 per violation or exclusion from participation in Federal health care programs for up to 5 years.

C. Professional Courtesy

The term ''professional courtesy'' is used to describe a number of analytically different practices. The traditional definition is the practice by a physician of waiving all or a part of the fee for services provided to the physician's office staff, other physicians, and/or their families. In recent times, ''professional courtesy'' has also come to mean the waiver of coinsurance obligations or other out-of-pocket expenses for physicians or their families (*i.e.,* ''insurance only'' billing), and similar payment arrangements by hospitals or other institutions for services provided to their medical staffs or employees. While only the first of these practices is truly ''professional courtesy,'' in the interests of clarity and completeness, we will address all three.

In general, whether a professional courtesy arrangement runs afoul of the fraud and abuse laws is determined by two factors: (i) How the recipients of the professional courtesy are selected; and (ii) how the professional courtesy is extended. If recipients are selected in a manner that directly or indirectly takes into account their ability to affect past or future referrals, the anti-kickback statute—which prohibits giving anything of value to generate Federal health care program business—may be implicated. If the professional courtesy is extended through a waiver of copayment obligations (*i.e.,* ''insurance only'' billing), other statutes may be implicated, including the prohibition of inducements to beneficiaries, section 1128A(a)(5) of the Act (codified at 42 U.S.C. 1320a–7a(a)(5)). Claims submitted as a result of either practice may also implicate the civil False Claims Act.

The following are general observations about professional courtesy arrangements for physician practices to consider:

- A physician's regular and consistent practice of extending professional courtesy by waiving the entire fee for services rendered to a group of persons (including employees, physicians, and/or their family members) may not implicate any of the OIG's fraud and abuse authorities so long as membership in the group receiving the courtesy is determined in a manner that does not take into account directly or indirectly any group member's ability to refer to, or otherwise generate Federal health care program business for, the physician.
- A physician's regular and consistent practice of extending professional courtesy by waiving otherwise applicable copayments for services rendered to a group of persons (including employees, physicians, and/or their family members), would not implicate the anti-kickback statute so long as membership in the group is determined in a

[12] This concern is noted in Advisory Opinion No. 98–4 and also the Office of Inspector General Compliance Program Guidance for Third-Party Medical Billing Companies. Both are available on the OIG web site at http://www.hhs.gov/oig.

manner that does not take into account directly or indirectly any group member's ability to refer to, or otherwise generate Federal health care program business for, the physician.

• Any waiver of copayment practice, including that described in the preceding bullet, does implicate section 1128A(a)(5) of the Act if the patient for whom the copayment is waived is a Federal health care program beneficiary who is not financially needy.

The legality of particular professional courtesy arrangements will turn on the specific facts presented, and, with respect to the anti-kickback statute, on the specific intent of the parties. A physician practice may wish to consult with an attorney if it is uncertain about its professional courtesy arrangements.

IV. Other Risk Areas

A. Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer

In February 2000, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at *www.hhs.gov/oig/frdalrt/index.htm*. The following is a summary of the Special Fraud Alert.

Among various relationships between physicians and labs, hospitals, home health agencies, etc., the OIG has identified potentially illegal practices involving the rental of space in a physician's office by suppliers that provide items or services to patients who are referred or sent to the supplier by the physician-landlord. An example of a suspect arrangement is the rental of physician office space by a durable medical equipment (DME) supplier in a position to benefit from referrals of the physician's patients. The OIG is concerned that in such arrangements the rental payments may be disguised kickbacks to the physician-landlord to induce referrals.

Space Rental Safe Harbor to the Anti-Kickback Statute

To avoid potentially violating the anti-kickback statute, the OIG recommends that rental agreements comply with all of the following criteria for the space rental safe harbor:

• The agreement is set out in writing and signed by the parties.

• The agreement covers all of the space rented by the parties for the term of the agreement and specifies the space covered by the agreement.

• If the agreement is intended to provide the lessee with access to the space for periodic intervals of time rather than on a full-time basis for the term of the rental agreement, the rental agreement specifies exactly the schedule of such intervals, the precise length of each interval, and the exact rent for each interval.

• The term of the rental agreement is for not less than one year.

• The aggregate rental charge is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

• The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

B. Unlawful Advertising

42 U.S.C. 1320b–10 makes it unlawful for any person to advertise using the names, abbreviations, symbols, or emblems of the Social Security Administration, Health Care Financing Administration, Department of Health and Human Services, Medicare, Medicaid or any combination or variation of such words, abbreviations, symbols or emblems in a manner that such person knows or should know would convey the false impression that the advertised item is endorsed by the named entities. For instance, a physician may not place an ad in the newspaper that reads ''Dr. X is a cardiologist approved by both the Medicare and Medicaid programs.'' A violation of this section may result in a penalty of up to $5,000 ($25,000 in the case of a broadcast or telecast) for each violation.

Appendix B: Criminal Statutes

This Appendix contains a description of criminal statutes related to fraud and abuse in the context of health care. The Appendix is not intended to be a compilation of all Federal statutes related to health care fraud and abuse. It is merely a summary of some of the more frequently cited Federal statutes.

I. Health Care Fraud (18 U.S.C. 1347)

Description of Unlawful Conduct

It is a crime to knowingly and willfully execute (or attempt to execute) a scheme to defraud any health care benefit program, or to obtain money or property from a health care benefit program through false representations. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of fines, imprisonment of up to 10 years, or both. If the violation results in serious bodily injury, the prison term may be increased to a maximum of 20 years. If the violation results in death, the prison term may be expanded to include any number of years, or life imprisonment.

Examples

1. Dr. X, a chiropractor, intentionally billed Medicare for physical therapy and chiropractic treatments that he never actually rendered for the purpose of fraudulently obtaining Medicare payments.

2. Dr. X, a psychiatrist, billed Medicare, Medicaid, TRICARE, and private insurers for psychiatric services that were provided by his nurses rather than himself.

II. Theft or Embezzlement in Connection with Health Care (18 U.S.C. 669)

Description of Unlawful Conduct

It is a crime to knowingly and willfully embezzle, steal or intentionally misapply any of the assets of a health care benefit program. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 10 years, or both. If the value of the asset is $100 or less, the penalty is a fine, imprisonment of up to a year, or both.

Example

An office manager for Dr. X knowingly embezzles money from the bank account for Dr. X's practice. The bank account includes reimbursement received from the Medicare program; thus, intentional embezzlement of funds from this account is a violation of the law.

III. False Statements Relating to Health Care Matters (18 U.S.C. 1035)

Description of Unlawful Conduct

It is a crime to knowingly and willfully falsify or conceal a material fact, or make any materially false statement or use any materially false writing or document in connection with the delivery of or payment for health care benefits, items or services. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 5 years, or both.

Example

Dr. X certified on a claim form that he performed laser surgery on a Medicare beneficiary when he knew that the surgery was not actually performed on the patient.

IV. Obstruction of Criminal Investigations of Health Care Offenses (18 U.S.C. 1518)

Description of Unlawful Conduct

It is a crime to willfully prevent, obstruct, mislead, delay or attempt to prevent, obstruct, mislead, or delay the communication of records relating to a Federal health care offense to a criminal investigator. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 5 years, or both.

Examples

1. Dr. X instructs his employees to tell OIG investigators that Dr. X personally performs all treatments when, in fact, medical technicians do the majority of the treatment and Dr. X is rarely present in the office.

2. Dr. X was under investigation by the FBI for reported fraudulent billings. Dr. X altered patient records in an attempt to cover up the improprieties.

V. Mail and Wire Fraud (18 U.S.C. 1341 and 1343)

Description of Unlawful Conduct

It is a crime to use the mail, private courier, or wire service to conduct a scheme to defraud another of money or property. The term ''wire services'' includes the use of a telephone, fax machine or computer. Each use of a mail or wire service to further fraudulent activities is considered a separate crime. For instance, each fraudulent claim that is submitted electronically to a carrier would be considered a separate violation of the law.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 5 years, or both.

Examples

1. Dr. X knowingly and repeatedly submits electronic claims to the Medicare carrier for office visits that he did not actually provide to Medicare beneficiaries with the intent to obtain payments from Medicare for services he never performed.

2. Dr. X, a neurologist, knowingly submitted claims for tests that were not reasonable and necessary and intentionally upcoded office visits and electromyograms to Medicare.

VI. Criminal Penalties for Acts Involving Federal Health Care Programs (42 U.S.C. 1320a–7b)

Description of Unlawful Conduct

False Statement and Representations

It is a crime to knowingly and willfully:

(1) make, or cause to be made, false statements or representations in applying for benefits or payments under all Federal health care programs;

(2) make, or cause to be made, any false statement or representation for use in determining rights to such benefit or payment;

(3) conceal any event affecting an individual's initial or continued right to receive a benefit or payment with the intent to fraudulently receive the benefit or payment either in an amount or quantity greater than that which is due or authorized;

(4) convert a benefit or payment to a use other than for the use and benefit of the person for whom it was intended;

(5) present, or cause to be presented, a claim for a physician's service when the service was not furnished by a licensed physician;

(6) for a fee, counsel an individual to dispose of assets in order to become eligible for medical assistance under a State health program, if disposing of the assets results in the imposition of an ineligibility period for the individual.

Anti-Kickback Statute

It is a crime to knowingly and willfully solicit, receive, offer, or pay remuneration of any kind (*e.g.,* money, goods, services):

- for the referral of an individual to another for the purpose of supplying items or services that are covered by a Federal health care program; or
- for purchasing, leasing, ordering, or arranging for any good, facility, service, or item that is covered by a Federal health care program.

There are a number of limited exceptions to the law, also known as ''safe harbors,'' which provide immunity from criminal prosecution and which are described in greater detail in the statute and related regulations (found at 42 CFR 1001.952 and www.hhs.gov/oig/ak). Current safe harbors include:

- investment interests;
- space rental;
- equipment rental;
- personal services and management contracts;
- sale of practice;
- referral services;
- warranties;
- discounts;
- employment relationships;
- waiver of Part A co-insurance and deductible amounts;
- group purchasing organizations;
- increased coverage or reduced cost sharing under a risk-basis or prepaid plan; and
- charge reduction agreements with health plans.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine of up to $25,000, imprisonment of up to 5 years, or both. In addition, the provider can be excluded from participation in Federal health care programs. The regulations defining the aggravating and mitigating circumstances that must be reviewed by the OIG in making an exclusion determination are set forth in 42 CFR part 1001.

Examples

1. Dr. X accepted payments to sign Certificates of Medical Necessity for durable medical equipment for patients she never examined.

2. Home Health Agency disguises referral fees as salaries by paying referring physician Dr. X for services Dr. X never rendered to the Medicare beneficiaries or by paying Dr. X a sum in excess of fair market value for the services he rendered to the Medicare beneficiaries.

Appendix C: Civil and Administrative Statutes

This Appendix contains a description of civil and administrative statutes related to fraud and abuse in the context of health care. The Appendix is not intended to be a compilation of all federal statutes related to health care fraud and abuse. It is merely a summary of some of the more frequently cited Federal statutes.

I. The False Claims Act (31 U.S.C. 3729–3733)

Description of Unlawful Conduct

This is the law most often used to bring a case against a health care provider for the submission of false claims to a Federal health care program. The False Claims Act prohibits knowingly presenting (or causing to be presented) to the Federal Government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the Federal Government or its agents, like a carrier, other claims processor, or State Medicaid program.

Definitions

False Claim—A ''false claim'' is a claim for payment for services or supplies that were not provided specifically as presented or for which the provider is otherwise not entitled to payment. Examples of false claims for services or supplies that were not provided specifically as presented include, but are not limited to:

- a claim for a service or supply that was never provided.
- a claim indicating the service was provided for some diagnosis code other than the true diagnosis code in order to obtain reimbursement for the service (which would not be covered if the true diagnosis code were submitted).
- a claim indicating a higher level of service than was actually provided.
- a claim for a service that the provider knows is not reasonable and necessary.
- a claim for services provided by an unlicensed individual.

Knowingly—To ''knowingly'' present a false or fraudulent claim means that the provider: (1) Has actual knowledge that the information on the claim is false; (2) acts in deliberate ignorance of the truth or falsity of the information on the claim; or (3) acts in reckless disregard of the truth or falsity of the information on the claim. It is important to note the provider does not have to deliberately intend to defraud the Federal Government in order to be found liable under this Act. The provider need only ''knowingly'' present a false or fraudulent claim in the manner described above.

Deliberate Ignorance—To act in ''deliberate ignorance'' means that the provider has deliberately chosen to ignore the truth or falsity of the information on a claim submitted for payment, even though the provider knows, or has notice, that information may be false. An example of a provider who submits a false claim with deliberate ignorance would be a physician who ignores provider update bulletins and thus does not inform his/her staff of changes in the Medicare billing guidelines or update his/her billing system in accordance with changes to the Medicare billing practices. When claims for non-reimbursable services are submitted as a result, the False Claims Act has been violated.

Reckless Disregard—To act in ''reckless disregard'' means that the provider pays no regard to whether the information on a claim submitted for payment is true or false. An example of a provider who submits a false claim with reckless disregard would be a physician who assigns the billing function to an untrained office person without inquiring whether the employee has the requisite knowledge and training to accurately file such claims.

Penalty for Unlawful Conduct

The penalty for violating the False Claims Act is a minimum of $5,500 up to a maximum of $11,000 for *each* false claim submitted. In addition to the penalty, a provider could be found liable for damages of up to three times the amount unlawfully claimed.

Examples

• A physician submitted claims to Medicare and Medicaid representing that he had personally performed certain services when, in reality, the services were performed by a nonphysician and they were not reimbursable under the Federal health care programs.

• Dr. X intentionally upcoded office visits and angioplasty consultations that were submitted for payment to Medicare.

• Dr. X, a podiatrist, knowingly submitted claims to the Medicare and Medicaid programs for non-routine surgical procedures when he actually performed routine, non-covered services such as the cutting and trimming of toenails and the removal of corns and calluses.

II. Civil Monetary Penalties Law (42 U.S.C. 1320a–7a)

Description of Unlawful Conduct

The Civil Monetary Penalties Law (CMPL) is a comprehensive statute that covers an array of fraudulent and abusive activities and is very similar to the False Claims Act. For instance, the CMPL prohibits a health care provider from presenting, or causing to be presented, claims for services that the provider ''knows or should know'' were:

• not provided as indicated by the coding on the claim;

• not medically necessary;

• furnished by a person who is not licensed as a physician (or who was not properly supervised by a licensed physician);

• furnished by a licensed physician who obtained his or her license through misrepresentation of a material fact (such as cheating on a licensing exam);

• furnished by a physician who was not certified in the medical specialty that he or she claimed to be certified in; or

• furnished by a physician who was excluded from participation in the Federal health care program to which the claim was submitted.

Additionally, the CMPL contains various other prohibitions, including:

• offering remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary to obtain items or services billed to Medicare or Medicaid from a particular provider;

• employing or contracting with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program.

The term ''should know'' means that a provider: (1) Acted in deliberate ignorance of the truth or falsity of the information; or (2) acted in reckless disregard of the truth or falsity of the information. The Federal Government does not have to show that a provider specifically intended to defraud a Federal health care program in order to prove a provider violated the statute.

Penalty for Unlawful Conduct

Violation of the CMPL may result in a penalty of up to $10,000 per item or service and up to three times the amount unlawfully claimed. In addition, the provider may be excluded from participation in Federal health care programs. The regulations defining the aggravating and mitigating circumstances that must be reviewed by the OIG in making an exclusion determination are set forth in 42 CFR part 1001.

Examples

1. Dr. X paid Medicare and Medicaid beneficiaries $20 each time they visited him to receive services and have tests performed that were not preventive care services and tests.

2. Dr. X hired Physician Assistant P to provide services to Medicare and Medicaid beneficiaries without conducting a background check on P. Had Dr. X performed a background check by reviewing the HHS–OIG List of Excluded Individuals/Entities, Dr. X would have discovered that he should not hire P because P is excluded from participation in Federal health care programs for a period of 5 years.

3. Dr. X and his oximetry company billed Medicare for pulse oximetry that they knew they did not perform and services that had been intentionally upcoded.

III. Limitations on Certain Physician Referrals (''Stark Laws'') (42 U.S.C. 1395nn)

Description of Unlawful Conduct

Physicians (and immediate family members) who have an ownership, investment or compensation relationship with an entity providing ''designated health services'' are prohibited from referring patients for these services where payment may be made by a Federal health care program unless a statutory or regulatory exception applies. An entity providing a designated health service is prohibited from billing for the provision of a service that was provided based on a prohibited referral. Designated health services include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

New regulations clarifying the exceptions to the Stark Laws are expected to be issued by HCFA shortly. Current exceptions articulated within the Stark Laws include the following, provided all conditions of each exception as set forth in the statute and regulations are satisfied.

Exceptions for Ownership or Compensation Arrangements

• physician's services;

• in-office ancillary services; and

• prepaid plans.

Exceptions for Ownership or Investment in Publicly Traded Securities and Mutual Funds

• ownership of investment securities which may be purchased on terms generally available to the public;

• ownership of shares in a regulated investment company as defined by Federal law, if such company had, at the end of the company's most recent fiscal year, or on average, during the previous 3 fiscal years, total assets exceeding $75,000,000;

• hospital in Puerto Rico;

• rural provider; and

• hospital ownership (whole hospital exception).

Exceptions Relating to Other Compensation Arrangements

• rental of office space and rental of equipment;

• bona fide employment relationship;

• personal service arrangement;

• remuneration unrelated to the provision of designated health services;

• physician recruitment;

• isolated transactions;

• certain group practice arrangements with a hospital (pre-1989); and

• payments by a physician for items and services.

Penalty for Unlawful Conduct

Violations of the statute subject the billing entity to denial of payment for the designated health services, refund of amounts collected from improperly submitted claims, and a civil monetary penalty of up to $15,000 for each improper claim submitted. Physicians who violate the statute may also be subject to additional fines per prohibited referral. In addition, providers that enter into an arrangement that they know or should know circumvents the referral restriction law may be subject to a civil monetary penalty of up to $100,000 per arrangement.

Examples

1. Dr. A worked in a medical clinic located in a major city. She also owned a free standing laboratory located in a major city. Dr. A referred all orders for laboratory tests on her patients to the laboratory she owned.

2. Dr. X agreed to serve as the Medical Director of Home Health Agency, HHA, for which he was paid a sum substantially above the fair market value for his services. In return, Dr. X routinely referred his Medicare and Medicaid patients to HHA for home health services.

3. Dr. Y received a monthly stipend of $500 from a local hospital to assist him in meeting practice expenses. Dr. Y performed no specific service for the stipend and had no obligation to repay the hospital. Dr. Y referred patients to the hospital for in-patient surgery.

IV. Exclusion of Certain Individuals and Entities From Participation in Medicare and other Federal Health Care Programs (42 U.S.C. 1320a–7)

Mandatory Exclusion

Individuals or entities convicted of the following conduct must be excluded from

participation in Medicare and Medicaid for a minimum of 5 years:

(1) a criminal offense related to the delivery of an item or service under Medicare or Medicaid;

(2) a conviction under Federal or State law of a criminal offense relating to the neglect or abuse of a patient;

(3) a conviction under Federal or State law of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct against a health care program financed by any Federal, State, or local government agency;

(4) a conviction under Federal or State law of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

If there is one prior conviction, the exclusion will be for 10 years. If there are two prior convictions, the exclusion will be permanent.

Permissive Exclusion

Individuals or entities convicted of the following offenses, may be excluded from participation in Federal health care programs for a minimum of 3 years:

(1) a criminal offense related to the delivery of an item or service under Medicare or Medicaid;

(2) a misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct against a health care program financed by any Federal, State, or local government agency;

(3) interference with, or obstruction of, any investigation into certain criminal offenses;

(4) a misdemeanor related to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance;

(5) exclusion or suspension under a Federal or State health care program;

(6) submission of claims for excessive charges, unnecessary services or services that were of a quality that fails to meet professionally recognized standards of health care;

(7) violating the Civil Monetary Penalties Law or the statute entitled ''Criminal Penalties for Acts Involving Federal Health Care Programs;''

(8) ownership or control of an entity by a sanctioned individual or immediate family member (spouse, natural or adoptive parent, child, sibling, stepparent, stepchild, stepbrother or stepsister, in-laws, grandparent and grandchild);

(9) failure to disclose information required by law;

(10) failure to supply claims payment information; and

(11) defaulting on health education loan or scholarship obligations.

The above list of offenses is not all inclusive. Additional grounds for permissive exclusion are detailed in the statute.

Examples

1. Nurse R was excluded based on a conviction involving obtaining dangerous drugs by forgery. She also altered prescriptions that were given for her own health problems before she presented them to the pharmacist to be filled.

2. Practice T was excluded due to its affiliation with its excluded owner. The practice owner, excluded from participation in the Federal health care programs for soliciting and receiving illegal kickbacks, was still participating in the day-to-day operations of the practice after his exclusion was effective.

Appendix D: OIG–HHS Contact Information

I. OIG Hotline Number

One method for providers to report potential fraud, waste, and abuse problems is to contact the OIG Hotline number. All HHS and contractor employees have a responsibility to assist in combating fraud, waste and abuse in all departmental programs. As such, providers are encouraged to report matters involving fraud, waste and mismanagement in any departmental program to the OIG. The OIG maintains a hotline that offers a confidential means for reporting these matters.

Contacting the OIG Hotline

By Phone: 1–800–HHS–TIPS (1–800–447–8477)
By E-Mail: *HTips@os.dhhs.gov*
By Mail: Office of Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW., Washington, DC 20201

When contacting the Hotline, please provide the following information to the best of your ability:

- Type of Complaint:

Medicare Part A
Medicare Part B
Indian Health Service
TRICARE
Other (please specify)

- HHS Department or program being affected by your allegation of fraud, waste, abuse/mismanagement:

Health Care Financing Administration (HCFA)
Indian Health Service
Other (please specify)

Please provide the following information. (However, if you would like your referral to be submitted anonymously, please indicate such in your correspondence or phone call.)

Your Name
Your Street Address
Your City/County
Your State
Your Zip Code
Your email Address

- Subject/Person/Business/Department that allegation is against.

Name of Subject
Title of Subject
Subject's Street Address
Subject's City/County
Subject's State
Subject's Zip Code

Please provide a brief summary of your allegation and the relevant facts.

II. Provider Self-Disclosure Protocol

The recommended method for a provider to contact the OIG regarding potential fraud or abuse issues that may exist in the provider's own organization is through the use of the Provider Self-Disclosure Protocol. This program encourages providers to voluntarily disclose irregularities in their dealings with Federal health care programs. While voluntary disclosure under the protocol does not guarantee a provider protection from civil, criminal, or administrative actions, the fact that a provider voluntarily disclosed possible wrongdoing is a mitigating factor in OIG's recommendations to prosecuting agencies. Although other agencies may not have formal policies offering immunity or mitigation for self-disclosure, they typically view self-disclosure favorably for the self-disclosing entity. Self-reporting offers providers the opportunity to minimize the potential cost and disruption of a full-scale audit and investigation, to negotiate a fair monetary settlement, and to avoid an OIG permissive exclusion preventing the provider from doing business with Federal health care programs. In addition, if the provider is obligated to enter into an Integrity Agreement (IA) as part of the resolution of a voluntary disclosure, there are three benefits the provider might receive as a result of self-reporting:

- If the provider has an effective compliance program and agrees to maintain its compliance program as part of the False Claims Act settlement, the OIG may not even require an IA;
- In cases where the provider's own audits detected the disclosed problem, the OIG may consider alternatives to the IA's auditing provisions. The provider may be able to perform some or all of its billing audits through internal auditing methods rather than be required to retain an independent review organization to perform the billing review; and
- Self-disclosing can help to demonstrate a provider's trustworthiness to the OIG and may result in the OIG determining that it can sufficiently safeguard the Federal health care programs through an IA without the exclusion remedy for a material breach, which is typically included in an IA.

Specific instructions on how a physician practice can submit a voluntary disclosure under the Provider Self-Disclosure Protocol can be found on the OIG's internet site at www.hhs.gov/oig or in the **Federal Register** at 63 FR 58399 (1998). A physician practice may, however, wish to consult with an attorney prior to submitting a disclosure to the OIG.

The Provider Self-Disclosure Protocol can also be a useful tool for baseline audits. The protocol details the OIG's views on the appropriate elements of an effective investigative and audit plan for providers. Physician practices can use the self-disclosure protocol as a model for conducting audits and self-assessments.

In relying on the protocol for audit design and sample selection, a physician practice should pay close attention to the sections on self-assessment and sample selection. These two sections provide valuable guidance regarding how these two functions should be performed.

The self-assessment section of the protocol contains information that can be applied to audit design. Self-assessment is an internal financial assessment to determine the

monetary impact of the matter. The approach of a review can include reviewing either all claims affected or a statistically valid sample of the claims.

Sample selection must include several elements. These elements are drawn from the Government sampling program known as RAT–STATS.[1] All of these elements are set forth in more detail in the Provider Self-Disclosure Protocol, but the elements are (1) Sampling unit, (2) sampling frame, (3) probe, (4) sample size, (5) random numbers, (6) sample design and (7) missing sample items. All of these sampling items should be clearly documented by the physician practice and compiled in the format set forth in the Provider Self-Disclosure Protocol. Use of the format set forth in the Provider Self-Disclosure Protocol will help physician practices to ensure that the elements of their internal audits are in conformance with OIG standards.

Appendix E: Carrier Contact Information

Medicare

A complete list of contact information (address, phone number, email address) for Medicare Part A Fiscal Intermediaries, Medicare Part B Carriers, Regional Home Health Intermediaries, and Durable Medical Equipment Regional Carriers can be found on the HCFA web site at *www.hcfa.gov/medicare/incardir.htm.*

Medicaid

Contact information (address, phone number, email address) for each State Medicaid carrier can be found on the HCFA web site at *www.hcfa.gov/medicaid/mcontact.htm.* In addition to a list of Medicaid carriers, the web site includes contact information for each State survey agency and the HCFA Regional Offices.

Contact information for each State Medicaid Fraud Control Unit can be found on the OIG web site at *www.hhs.gov/oig/oi/mfcu/index.htm.*

Appendix F: Internet Resources

Office of Inspector General—U.S. Department of Health and Human Services

www.hhs.gov/oig

This web site includes a variety of information relating to Federal health care programs, including the following:
Advisory Opinions
Anti-kickback Information
Compliance Program Guidance
Corporate Integrity Agreements
Fraud Alerts

Links to web pages for the:
Office of Audit Services (OAS)
Office of Evaluation and Inspections (OEI)
Office of Investigations (OI)
OIG List of Excluded Individuals/Entities
OIG News
OIG Regulations
OIG Semi-Annual Report
OIG Workplan

Health Care Financing Administration

www.hcfa.gov

This web site includes information on a wide array of topics, including the following:

Medicare

National Correct Coding Initiative
Intermediary-Carrier Directory
Payment
Program Manuals
Program Transmittals & Memorandum
Provider Billing/HCFA Forms
Statistics and Data

Medicaid

HCFA Regional Offices
Letters to State Medicaid Directors
Medicaid Hotline Numbers
Policy & Program Information
State Medicaid Contacts
State Medicaid Manual
State Survey Agencies
Statistics and Data

HCFA Medicare Training

www.hcfa.gov/medlearn

This site provides computer-based training on the following topics:
HCFA 1500 Form
Fraud & Abuse
ICD–9–CM Diagnosis Coding
Adult Immunization
Medicare Secondary Payer (MSP)
Women's Health
Front Office Management
Introduction to the World of Medicare
Home Health Agency
HCFA 1450 (UB92)

Government Printing Office

www.access.gpo.gov

This site provides access to Federal statutes and regulations pertaining to Federal health care programs.

The U.S. House of Representatives Internet Library

uscode.house.gov/usc.htm

This site provides access to the United States Code, which contains laws pertaining to Federal health care programs.

[FR Doc. 00–25500 Filed 10–4–00; 8:45 am]

BILLING CODE 4152–01–P

[1] Available through the OIG web site at http://www.hhs.gov/oas/ratstat.html.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: President's Cancer Panel.

Date: October 12–13, 2000.

Time: 9:00 AM to 4:00 PM.

Agenda: Town Hall Meeting. Topic will be Improving Cancer Care for All: Real People—Real Problems.

Place: Radisson Northern Hotel, 19 North 28th Street, Billings, MT 59101.

Contact Person: Maureen O. Wilson, Executive Secretary, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 4A48, Bethesda, MD 20892, 301/496–1148.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 26, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–25538 Filed 10–4–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: October 17–18, 2000.

Time: 8 AM to 12:30 PM.

Agenda: To discuss NCI's activities related to Health Disparities and Quality of Care, and Update on the Office of Communications reorganization regarding DCLG activities, including reports from the working groups.

Place: National Cancer Institute, 6116 Executive Boulevard, Suite 300C, Rockville, MD 20852.

Contact Person: Elaine Lee, Acting Executive Secretary, Office of Liaison Activities, National Institutes of Health,

Self-Audit Snapshot

A self-audit is an audit, examination, review, or other inspection performed by and within a physician's or other health care professional's business. Self-audits generally focus on assessing, correcting, and maintaining controls to promote compliance with applicable laws, rules, and regulations. The U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG), includes periodic internal monitoring and auditing in its list of the seven elements of an effective compliance program.[1]

States may require provider self-audits as a way to identify additional overpayments. For example, New Mexico uses provider self-audits to capture more improper payments than program integrity staff could do through State-initiated audits and investigations.[2] A self-audit is a useful tool for providers in reducing noncompliance. Self-audits can help:

- Reduce fraud and improper payments;
- Improve patient care;
- Lower the chances of an external audit; and
- Create a robust culture of compliance.

HHS-OIG recommends providers start with a baseline audit of the claims development and submission process.[3] The audit should cover a period of at least 3 months and include a random sample selection of between 5 and 10 Medicaid records per professional who bills Medicaid services.[4] Helpful details on how to collect a statistically valid random sample are set forth in HHS-OIG's Provider Self-Disclosure Protocol.[5] A designated staff member who understands documentation and coding principles should then review the sample claims and medical records "for compliance with applicable coding, billing and documentation requirements." The professional who rendered the care should not review his or her own records. Providers should use the results of the baseline audit to identify the areas that should be the subject of ongoing monitoring and periodic self-audits.[6]

In the course of a self-audit, if a provider uncovers possible fraud or material noncompliance with Medicaid requirements, they should self-disclose the information. Many States offer provider self-disclosure protocols.[7, 8] Another option is the OIG self-disclosure process posted to https://oig.hhs.gov/compliance/self-disclosure-info/ on the HHS-OIG website. Potential benefits of self-disclosure may include lower damage amounts than are sought in government-initiated investigations, less potential exposure under False Claims laws, and possible release from exclusions and corporate integrity measures.[9] Under the OIG self-disclosure process, if providers find improper claims for Federal health care dollars, they must return any overpayments within 60 days of identification and conduct either a census or a random sample of 100 claims.[10] Providers can submit self-disclosure information to HHS-OIG online, by mail, or by fax, but they should not report it to the OIG Hotline.[11]

For More Information

For more information on self-audits, see the "Self-Audit" Toolkit posted to https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html on the CMS website. The electronic version of this and other E-Bulletins and additional program integrity information can also be found there.

Follow us on Twitter #MedicaidIntegrity

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2 Centers for Medicare & Medicaid Services. Center for Program Integrity. Medicaid Integrity Program Annual Summary Report of Comprehensive Program Integrity Reviews. (2014, June). Retrieved June 30, 2016, from https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/fraudabuseforprofs/downloads/2013pisummary.pdf

3 Federal Register Vol. 65, No. 194. (2000, October 5). Office of Inspector General. OIG Compliance Program for Individual and Small Group Physician Practices. Retrieved June 28, 2016, from https://oig.hhs.gov/authorities/docs/physician.pdf

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10 U.S. Department of Health and Human Services. Office of Inspector General. (2013, April 17). Updated: OIG's Provider Self-Disclosure Protocol (p. 2). Retrieved July 1, 2016, from https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf

11 U.S. Department of Health and Human Services. Office of Inspector General. Self-Disclosure Information. Retrieved July 1, 2016, from https://oig.hhs.gov/compliance/self-disclosure-info/index.asp

Disclaimer

This E-Bulletin was current at the time it was published or uploaded onto the web. Medicaid and Medicare policies change frequently so links to the source documents have been provided within the document for your reference.

This E-Bulletin was prepared as a service to the public and is not intended to grant rights or impose obligations. This E-Bulletin may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. Use of this material is voluntary. Inclusion of a link does not constitute CMS endorsement of the material. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

August 2016

mln
FACT SHEET
KNOWLEDGE • RESOURCES • TRAINING

Complying with Medical Record Documentation Requirements

What's Changed?

Note: No substantive content updates.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

CMS uses the Comprehensive Error Rate Testing (CERT) program to measure improper payments in the Medicare Fee-for-Service (FFS) Program. Under CERT, we review a random sample of Medicare FFS claims to determine if we paid them correctly under Medicare coverage, coding, and billing rules.

Once the CERT program identifies a claim in the sample, it requests (via fax, letter, or phone call) the associated medical records and other related documentation from the provider or supplier who submitted the claim. CERT medical review professionals then examine the claim and related documentation.

The CERT program is managed by 2 contractors:

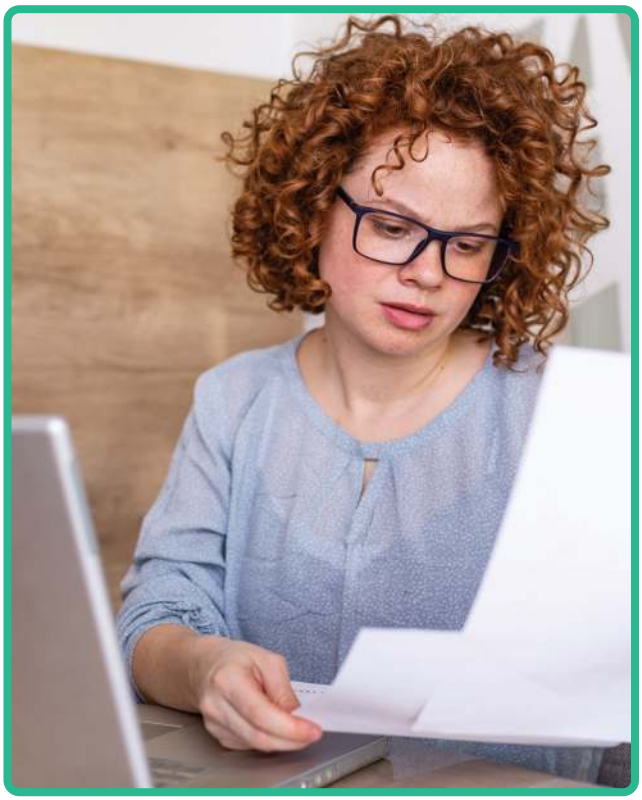
- The CERT Statistical Contractor determines how claims are sampled and calculates any improper payments
- The CERT Review Contractor requests and reviews medical records from providers and suppliers

Submit enough documentation to support your claims.

Third-Party Additional Documentation Requests

When CERT requests a review, the billing provider must get supporting documentation (for example, physician's order or notes to support medical necessity) from a referring physician's office or from an inpatient facility, skilled nursing facility, or other location where records (for example, progress notes) are kept to support the services billed, ordered, or provided.

The billing provider should submit the requested documentation because they're the enity whose payment CERT reviews.



We pay for necessary services, but patient medical record documentation must show their medical necessity. Instruct medical record staff and third-party medical record copy services to provide all records that support payment. This may include records for services before the date of services listed on the medical record request. Examples include:

- A signed office note from a previous visit where the provider ordered a diagnostic or other service
- The care plan written by the supervising physician who bills for an "incident to" service
- For incident to services, the care plan written by the supervising physician or non-physician practitioner (NPP)
- Lab orders for recurring tests to meet the specific needs of an individual patient

Insufficient Documentation Errors

CERT reviewers determine claims have errors when the medical documentation submitted is insufficient to support Medicare payment for the services billed (that is, the reviewer couldn't conclude some of the allowed services were actually provided, were provided at the level billed, or were medically necessary).

Reviewers also place claims into this category when a specific documentation element that's required as a condition of payment is missing, like a physician signature on an order, or a form that's not entirely completed.

CERT identifies insufficient documentation errors that may include:

- Incomplete progress notes (for example, unsigned, undated, insufficient detail)
- Unauthenticated medical records (for example, no provider signature, no supervising signature, illegible signatures without a signature log or attestation to identify the signer, and an electronic signature without the electronic record protocol or policy that documents the process for electronic signatures)
- No documentation of intent to order services and procedures (for example, incomplete or missing signed order or progress note describing intent for services to be provided)

Common Procedures with Insufficient Documentation Errors

Vertebral Augmentation Procedures

- Missing signature and date on clinical documentation that supports the patient's symptoms
- No radiographs that support the procedure's medical necessity
- Insufficient medical record documentation (for example, medication administration records, therapy discharge summary) that the provider tried conservative medical management, but it failed or was contraindicated
- No signed and dated attestation statement for the operative report if a physician signature was missing or illegible (or missing the operative report if the statement is electronically signed)

Physical Therapy Services

- Documentation didn't support certification of the plan of care for physical therapy services
- We require the physician's or NPP's signature and date of certification of the plan of care or progress note indicating they reviewed and approved the plan of care

Evaluation & Management (E/M) Services

- CERT identified office visits (established), hospital (initial), and hospital (subsequent) as the top 3 errors in E/M service categories
- High errors consisted of insufficient documentation, medical necessity, and incorrect coding of E/M services to support medical necessity and accurate billing of those services

Durable Medical Equipment (DME)

- Certain DME HCPCS codes (like hospital beds, glucose monitors, and manual wheelchairs) require a valid standard written order prior to claim submission
- The practitioner's name or NPI must be on the valid standard written order
- We'll pay claims only for DME if the ordering physician and DME supplier are actively enrolled in Medicare on the date of service
- As a condition for payment, a physician, physician assistant, nurse practitioner, or certified nurse specialist must document a face-to-face encounter exam with a patient in the 6 months before the written order for certain DME items

Computed Tomography (CT) Scans

- Documentation of the plan or intent to order a CT scan was insufficient to support its medical necessity
- If the handwritten signature is illegible, include a signature log (if electronic, include the protocol)

Provider Compliance has more information about how to avoid common coverage, coding, and billing errors.

Resources

- Section 220.1.3 of the Medicare Benefit Policy Manual, Chapter 15: Certification and Recertification of Need for Treatment and Therapy Plans of Care
- Section 220.4 of the Medicare Benefit Policy Manual, Chapter 15: Functional Reporting
- Section 220.1.1 of the Medicare Benefit Policy Manual, Chapter 15: Care of a Physician/ Nonphysician Practitioner (NPP)
- Complying with Medicare Signature Requirements
- Section 3.3.2.4 of the Medicare Program Integrity Manual, Chapter 3: Signature Requirements
- Section 30.6 of the Medicare Claims Processing Manual, Chapter 12: Evaluation and Management Service Codes - General (Codes 99202–99499)
- Medicare Coverage Database
- Section 80.6 of the Medicare Benefit Policy Manual, Chapter 15: Requirements for Ordering and Following Orders for Diagnostic Tests
- Complying with Documentation Requirements for Lab Services

The Medicare Learning Network® and the Comprehensive Error Rate Testing (CERT) Part A and Part B (A/B) and Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Outreach & Education Task Force developed this content together to provide nationally consistent education to health care providers.

mln FACT SHEET
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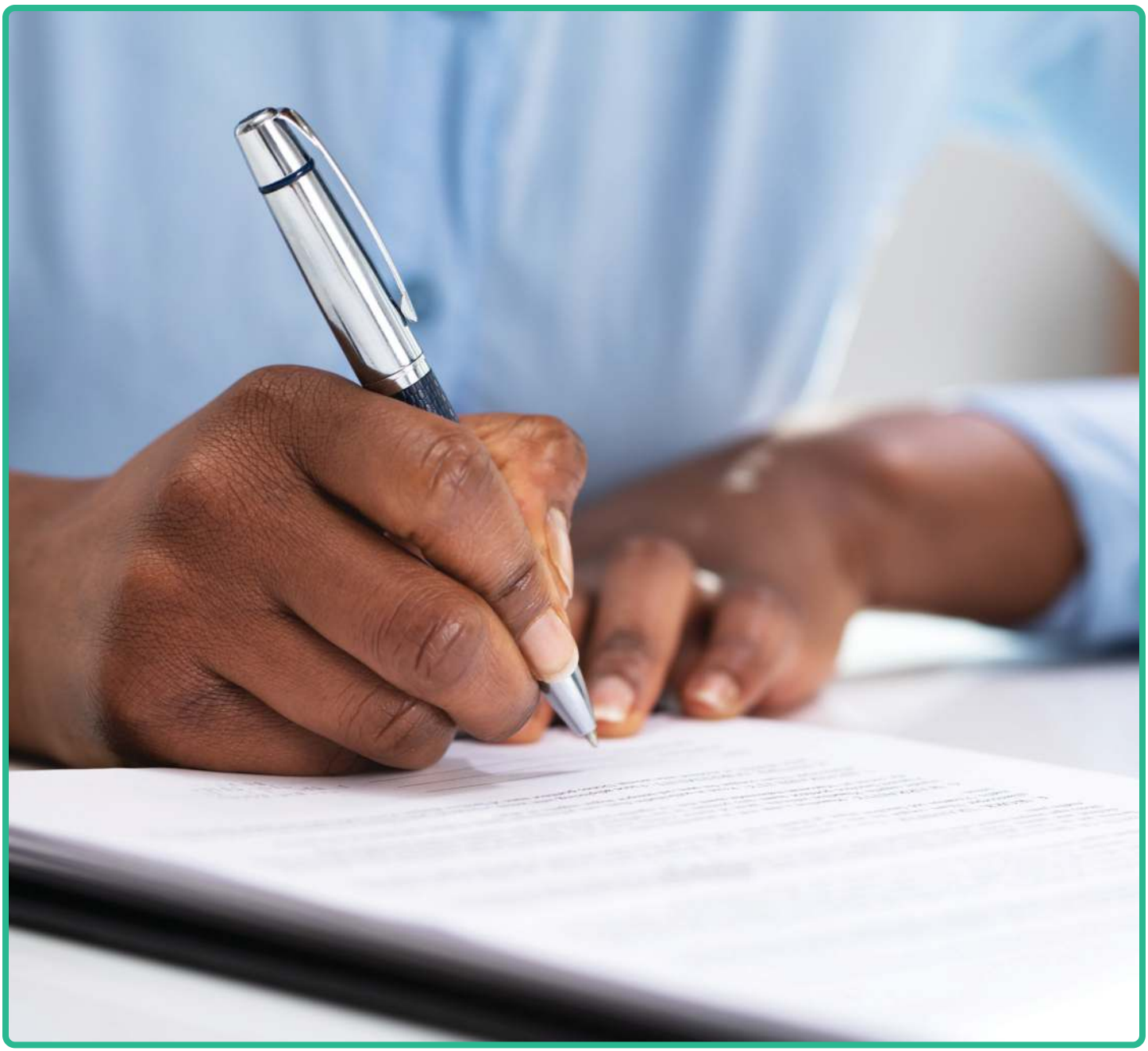
Print-Friendly Version

Complying with Medicare Signature Requirements



CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

What's Changed?

- Added information about signing documentation written by a medical student

You'll find substantive content updates in dark red font.

Introduction

CMS started the Comprehensive Error Rate Testing (CERT) Program to measure improper payments in the Medicare Fee-for-Service (FFS) Program. Under CERT, we review a random sample of all Medicare FFS claims to determine if we paid them properly under Medicare coverage, coding, and billing rules.

Two contractors manage the CERT Program: CERT Statistical Contractor (CERT SC) and CERT Review Contractor (CERT RC).

The CERT SC determines Medicare claims sampling and calculates the improper payment. Visit the CMS CERT webpage to review CERT Improper Payments Reports.

The Medicare Learning Network® (MLN), with the CERT Part A and Part B (A/B) and Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Outreach & Education Task Forces, developed this fact sheet to describe common CERT Program signature requirements errors. It helps providers and their clinical and office staff understand documentation supporting a Medicare claim for medical services and supplies.

Medicare Signature Requirements

Documentation must meet Medicare's signature requirements. Medicare claims reviewers look for signed and dated medical documentation meeting Medicare signature requirements. If entries aren't signed and dated, they may deny the associated claims.

FAQs

How do we define a handwritten signature?

A mark or sign the ordering or prescribing physician or Non-Physician Practitioner (NPP) makes on a document signifies knowledge, approval, acceptance, or obligation.

What if I use a scribe when documenting medical record entries?

Even if a scribe dictates the entry on your behalf, you must sign the entry to effectively authenticate the documents and care you provided or ordered. It's unnecessary to document who transcribed the entry.

What is required for a valid signature?

A valid signature must be:

- For services you provided or ordered
- Handwritten or electronic
  - We allow stamped signatures if you have a physical disability and can prove to a CMS contractor you're unable to sign due to that disability
- Legible or can be confirmed by comparing to a signature log or attestation statement

How do we treat orders differently than other medical documentation?

Orders communicate the need for a patient to get a test, procedure, or piece of equipment. Sign orders promptly, and in some cases, **before starting the service**.

Unsigned orders in those situations aren't subject to signature attestation, and the reviewer will disregard them. You can't create missing orders after the fact to backdate a plan of care or other service. If there's no order in the submitted medical record, Medicare will deny payment.

There are some exceptions—for example, we may accept unsigned orders for clinical diagnostic tests if a signed progress note in the record indicates the practitioner's intent to order the test. Get more information on orders at Medicare Benefit Policy Manual, Chapter 15, Section 80.6.1.

Medical documentation includes notes, lab results, clinical observations, and orders.

What should I do if I didn't sign an order or medical record?

You can't add late signatures to orders or medical records (beyond the short delay that happens during the transcription process). We don't accept retroactive orders.

If your signature is missing from the medical record (other than an order), send an attestation statement. We accept a signature attestation for medical documentation, except orders. The attestation must be associated with a medical record and created by the author. Attestations may be considered, regardless of their creation date, unless the regulation or policy indicates the signature must be in place before a given event or date.

Your MAC may offer specific guidance on signature attestation statements, including whether current laws or regulations allow attestation for missing signatures in certain situations.

Do I need to re-document a medical student's documentation of an Evaluation & Management (E/M) visit before I sign the record?

If you rely on the medical student's documentation, it's unnecessary to re-document the E/M service, but you **must** review and verify (sign and date) the student's medical record entry.

What if I signed the order or progress note but my signature isn't legible?

You or your organization may send a signature log or attestation statement to support the identity of any illegible signatures. A printed signature below the illegible signature in the original record is acceptable.

What is a signature log?

A signature log is a typed listing of physicians and NPPs showing their names with a corresponding handwritten signature. This is an individual log or a group log. A signature log shows signature identity throughout the medical record. We encourage, but don't require, physicians and NPPs to list their credentials in the log.

What if I don't have a signature log in place?

You or your organization may create a signature log at any time. CMS contractors accept all sent signature logs regardless of the date you created them.

Can I avoid delays in claim reviews by sending a signature log or signature attestation with my documentation?

We encourage you to send a complete medical record with proper signature documentation first to avoid medical review delays. This includes a signature log or attestation if needed.

Must I date my signatures?

Documentation must have enough information to show the date you ordered or performed the services. If you dated the entries immediately above and below an undated entry, medical review may reasonably assume the entry date in question.

What are the medical review guidelines for using an electronic signature?

The medical review guidelines for using an electronic signature are:

- Systems and software products must include protections against modification, and you should apply administrative safeguards that meet all standards and laws.
- The individual's name on the alternate signature method and the provider accept responsibility for the authenticity of attested information.
- Order Part B medications, other than controlled substances, through a qualified e-prescribing system.
- Order medications incident to DME, other than controlled substances, through a qualified e-prescribing system. Reviewers shouldn't require the provider produce hardcopy pen and ink signatures as evidence of a medication order.

Check with your attorneys and malpractice insurers before using alternative signature methods.

Resources

- Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4
- MLN Matters® Article SE1419, Medicare Signature Requirements: Educational Resources for Health Care Professionals

The Comprehensive Error Rate Testing (CERT) Part A and Part B (A/B) and Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Outreach & Education Task Forces are independent from the Centers for Medicare & Medicaid Services (CMS) CERT team and CERT contractors, which are responsible for calculation of the Medicare Fee-for-Service improper payment rate.

mln Educational Tool
KNOWLEDGE • RESOURCES • TRAINING

Medicare Documentation Job Aid for Chiropractic Doctors

What's Changed?

No substantive content updates.

Did you get a request from a Medicare contractor for chiropractic documentation? This tool will help you respond to documentation requests.

Documentation Basics

Chiropractic documentation should include:

Patient Information

- ☐ Include the patient's name and date of service on all documentation

Subluxation Documentation Requirements

- ☐ Include documentation of subluxation shown by x-ray or physical exam:
  - ☐ Include a CT scan and or MRI showing subluxation of spine
  - ☐ Include documentation of your review of the x-ray, MRI, or CT, noting level of subluxation
  - ☐ Include x-rays taken within 12 months before or 3 months following the beginning of treatment
    - In some cases of chronic subluxation (for example, scoliosis), Medicare may accept an older x-ray if the patient's health record shows the condition existed longer than 12 months and it's reasonable to conclude the condition is permanent

Or

- ☐ Include documentation of subluxation shown by physical examination. Documentation must show at least 2 elements of:
  - ☐ Pain
  - ☐ Asymmetry/misalignment
  - ☐ Range of motion abnormality
  - ☐ Tissue tone changes (P.A.R.T.), including 1 that falls under asymmetry/misalignment or range of motion abnormality
  - ☐ Include dated documentation of the first evaluation
  - ☐ Include primary diagnosis of subluxation (including level of subluxation)
- ☐ Include any documentation supporting medical necessity

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Initial Evaluation

- ☐ History
  - ☐ Date of initial treatment.
  - ☐ Description of current illness.
  - ☐ Symptoms related to level of subluxation causing patient to seek treatment.
  - ☐ Family history (recommended).
  - ☐ Past health history (recommended).
  - ☐ Mechanism of trauma (recommended).
  - ☐ Quality and character of symptoms or problem (recommended).
  - ☐ Onset, duration, intensity, frequency, location, and radiation of symptoms (recommended).
  - ☐ Aggravating or relieving issues (recommended).
  - ☐ Past interventions, treatments, medication, and secondary complaints (recommended).
- ☐ Contraindications (for example, risk of injury to patient from dynamic thrust or discussion of risk with patient) (recommended).
- ☐ Physical examination (P.A.R.T.).
  - ☐ Evaluation of musculoskeletal and nervous system through physical examination.
- ☐ Treatment given on day of visit (if relevant).
  - ☐ Include specific areas and levels of the spine that you manipulated.
  - ☐ Medicare may cover treatment using hand-held devices. But Medicare doesn't offer more payment or recognize an extra charge for use of the device.

Treatment Plan

- ☐ Frequency and duration of visits (recommended)
- ☐ Specific treatment goals (recommended)
- ☐ Objective measures to evaluate treatment effectiveness (recommended)

Subsequent Visits

- ☐ History
  - ☐ Review of chief complaint
  - ☐ Changes since last visit
  - ☐ System review, if relevant
- ☐ Physical examination (P.A.R.T.)
  - ☐ Assessment of change in patient's condition since last visit
  - ☐ Evaluation of treatment effectiveness
- ☐ Treatment given on day of visit (include specific areas and levels of spine that you manipulated)

General Guidelines

- ☐ Make sure medical records show that the service is a corrective treatment, not a maintenance treatment.
  - ☐ For Medicare purposes, place an AT modifier on a claim when you give active or corrective treatment for acute or chronic subluxation.
    - Don't use an AT modifier for maintenance therapy.
    - Only use an AT modifier when chiropractic manipulation is reasonable and necessary as defined by national and local policy.
    - **Note:** An AT modifier doesn't prove the service is reasonable and necessary. As always, contractors can deny a claim after medical review.

      Make sure you know these policies, along with any local coverage determination in your area, to better understand how active or corrective chiropractic services are covered.
- ☐ Include records for all dates of service on a claim.
- ☐ Make sure documentation is legible and complete, including signatures.
- ☐ Include legible signatures and credentials of professionals providing services.
  - ☐ If signatures are missing or illegible, include a completed signature attestation statement.
  - ☐ For illegible signatures, include a signature log.
  - ☐ For electronic health records, include a copy of electronic signature policy and procedures describing how notes and orders are signed and dated. Validating electronic signatures depends on getting this information.
- ☐ Include abbreviation key (if relevant).
- ☐ Include any other documentation to support medical necessity of services billed, as well as documentation specifically asked for in an additional documentation request (ADR) letter.
- ☐ Include a copy of the Advance Beneficiary Notice of Noncoverage (if relevant).

Resources

- Medicare Benefit Policy Manual, Chapter 15, Sections 30.5 and 240
- Medicare Claims Processing Manual, Chapter 12, Section 220
- MLN Matters® SE1601 Medicare Coverage for Chiropractic Services – Medical Record Documentation Requirements for Initial and Subsequent Visits
- MLN Matters® SE1603 Educational Resources to Assist Chiropractors with Medicare Billing

DEPARTMENMT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Official Information Health Care Professionals Can Trust

Misinformation on Chiropractic Services

Background

This fact sheet is being provided by the Centers for Medicare & Medicaid Services (CMS) to correct misinformation in the chiropractic community relating to Medicare and its regulations as they relate to chiropractic services. This fact sheet is informational only and represents no changes to existing Medicare policy.

CMS is providing this fact sheet in order to clarify specific issues. The issues being addressed are as follows:

Misinformation #1: There is a 12 visit cap or limit for chiropractic services.

Correction: There are no caps/limits in Medicare for covered chiropractic care rendered by chiropractors who meet Medicare's licensure and other requirements as specified in the Medicare Benefit Policy Manual, Chapter 15, Section 30.5 (this manual is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html** on the CMS website). Your claims contractor may have review screens (numbers of visits at which the Medicare Carrier or A/B MAC might require a review of documentation before allowing further care), but caps/limits are not allowed.

Misinformation #2: If you are a non-participating (non-par) provider, you do not have to worry about billing Medicare.

Correction: Being non-par does not mean you don't have to bill Medicare. All Medicare part B covered services must be billed to Medicare by the provider or the provider could face penalties. This is known as the "Mandatory Claim Submission Rule" (an exception to this is when the beneficiary has signed a valid Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, with Option #2 selected—see "Misinformation #5" for further information).

A non-par provider is actually someone who has enrolled to be a Medicare provider but chooses to receive payment in a different method and amount than Medicare providers classified as participating. Non-par providers may receive reimbursement for rendered services directly from their Medicare patients; however, they still must submit a bill to Medicare so the beneficiary may be reimbursed for the portion of the charges for which Medicare is responsible.

It is important to note that non-par providers may also choose to accept assignment; therefore, the amount paid by the beneficiary must be reported in Item 29 of the CMS 1500 claim form or its electronic equivalent. This ensures that the beneficiary is reimbursed (if applicable) prior to Medicare sending payment to the provider.

ICN #006953 October 2013

Whether or not non-par providers choose to accept assignment on all claims or on a claim-by-claim basis, Medicare reimbursement is five percent less than for a participating provider, as reflected in the annual Medicare Physician Fee Schedule.

You can find a copy of the Medicare Participating Provider Agreement at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms460.pdf on the CMS website. The form contains important information regarding the participation process and the annual opportunity you have to make or change your participation decision. Additional information is available in the Medicare Benefit Policy Manual (Chapter 15; Covered Medical and Other Health Services) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf and the Medicare Claims Processing Manual (Chapter 12; Physician/Nonphysician Practitioners) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf on the CMS website.

Misinformation #3: If you are a non-par provider, you will never be audited nor have claims reviewed, etc.

Correction: Any Medicare claim submitted can be audited/reviewed; the participation status of the physician does not affect the possibility of this occurring. CMS audits/reviews are intended to protect Medicare trust funds and also to identify billing errors so providers and their billing staff can be alerted of errors and educated on how to avoid future errors. Correct coverage, reimbursement, and billing requirements are readily available to assist you in understanding Medicare requirements.

This information is in Medicare manuals that are at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html on the CMS website. In addition, an excellent way to stay informed about changes to Medicare billing and coverage requirements is to monitor MLN Matters® Articles, which are available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html on the same site.

Misinformation #4: You can opt out of Medicare.

Correction: Doctors of Chiropractic (DC) may not opt out of Medicare. Note that opting out and being non-participating are not the same things. Chiropractors may decide to be participating or non-participating with regard to Medicare, but they may not opt out. (Opt out refers to physicians' ability to decide not to bill Medicare at all and then entering into private contracts with Medicare beneficiaries they treat. Services furnished under these private contracts that meet the opt out requirements are not covered services under Medicare and no payment is made for those services by Medicare.)

For further discussions of the Medicare "opt out" provision, see the Medicare Benefit Policy Manual (Chapter 15, Section 40; Definition of Physician/Practitioner) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf on the CMS website.

Misinformation #5: You should get an Advance Beneficiary Notification (ABN) signed once for each patient and it will apply to all services, all visits.

Correction: The decision to deliver an ABN to a beneficiary must be based on the expectation that Medicare will not pay for a particular service because that service will not be considered medically reasonable and necessary in this instance. The ABN then allows the beneficiary to make an informed decision about receiving and paying for the service.

The ABN has 3 option boxes, and the beneficiary must choose one before signing the ABN for it to be considered valid liability notification.

- **Option #1:**
  If the beneficiary selects option #1, s/he is agreeing to pay out of pocket for the service in question and requests that the chiropractor file a claim for that service with Medicare. With option #1 selected, the beneficiary retains appeals rights if s/he disagrees with Medicare's claim decision. The chiropractor is permitted to ask for payment from the

beneficiary before the claim is filed if option #1 is chosen. (Beneficiaries who have secondary insurance may need a Medicare denial on a claim to enable reimbursement from their secondary insurance plan.)

- **Option #2:**
  A beneficiary selects option #2 when s/he agrees to pay out of pocket for the service in question and does not want a claim sent to Medicare. In accordance with the ABN, the provider would not file a claim, and the beneficiary would not have appeal rights since no claim is being submitted. (Please note that the patient can change his/her mind at a future time and request the claim be submitted.)

- **Option #3:**
  Option #3 is selected by the beneficiary who chooses not to receive and pay for the service. No service is rendered, and no claim is filed. Since no claim is filed, the patient cannot appeal to Medicare for a payment decision.

An ABN is issued each time a patient receives a Medicare covered service that the provider believes might be considered not medically reasonable and necessary and thus not payable by Medicare. Providers may issue a single ABN to a patient receiving the same service multiple times on a continuing basis (e.g., lumbar spinal manipulation monthly for a year). ABNs for repetitive services can be effective for up to one year. The ABN for ongoing services must describe the specific service(s) and frequency of delivery. If delivery of the repetitive service exceeds one year or the service provided changes, a new ABN must be issued. When a beneficiary with an ABN on file for repetitive services receives a different service that is not listed on the ABN, and for which Medicare payment is not expected, a separate ABN must be issued for the service which is not listed.

For further information, see the Medicare Claims Processing Manual (Chapter 30) at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf** and the Medicare Benefit Policy Manual (Chapter 15) at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf** on the CMS website. Also see the booklet titled "Advance Beneficiary Notice of Non-Coverage (ABN) Part A and Part B" at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/abn_booklet_icn006266.pdf** on the CMS website.

Misinformation #6: Maintenance care is not a covered service under Medicare.

Correction: Spinal manipulation is a covered service under Medicare. However, maintenance care is not considered by Medicare to be medically reasonable and necessary, and is not reimbursable by Medicare.

Only acute and chronic spinal manipulation services are considered active care and may, therefore, be reimbursable. Maintenance therapy is defined (per Chapter 15, Section 30.5.B. of the Medicare Benefit Policy Manual) as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, the treatment is then considered maintenance therapy.

See MM3449 (Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy) at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3449.pdf** on the CMS website. This article contains important information on completing claims and how to identify acute and chronic adjustments as opposed to maintenance adjustments. When a

maintenance spinal manipulation treatment is being provided, the ABN must be issued before the service is rendered. Additional details are available in the Medicare Benefit Policy Manual, Chapter 15, Section 30.5 (Chiropractor's Services) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf on the CMS website.

Misinformation #7: Non-par providers do not have the same documentation requirements as par providers.

Correction: Chiropractic care has documentation requirements. The participating status of the provider is irrelevant to the documentation requirements.

Specific details regarding documentation requirements are in the Medicare Benefit Policy Manual (Chapter 15, Sections 30.5 and 240) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf on the CMS website. Also, see the Medicare Claims Processing Manual (Chapter 12, Section 220) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf on the CMS website.

Misinformation #8: DME ordered by a DC will be reimbursed by CMS.

Correction: A chiropractor may act as supplier of durable medical equipment (DME) if they have a valid supplier number assigned by the National Supplier Clearinghouse, but a chiropractor will not be reimbursed if they order DME.

Additional Information

If you have any questions regarding chiropractic issues and Medicare, please contact your Medicare Carrier or A/B MAC at its toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.

The Social Security Act (Section 1862 (a)(1) at http://www.ssa.gov/OP_Home/ssact/title18/1862.htm on the Internet) provides that Medicare will only pay for items or services it determines to be "reasonable and necessary" and, if those items or services can be shown to be "reasonable and necessary," then those items or services are covered and will be paid by Medicare.

Check out CMS on:

Twitter, LinkedIn, YouTube, and Flickr

Reasonable & Necessary Guidelines

In the absence of a Local Coverage Determination (JH)(JL), National Coverage Determination (NCD) , or the Centers for Medicare & Medicaid Services Manual Instruction, reasonable and necessary guidelines still apply.

Section 1862(a) (1) (A) of the Social Security Act directs the following:

"No payment may be made under Part A or Part B for any expenses incurred for items or services not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Note: malformed is defined as (of a person or part of the body) abnormally formed; misshapen.

The Medicare Administrative Contractor will determine if an item or service is "reasonable and necessary" under §1862(a) (1) (A) of the Act if the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency in terms of whether the service or item is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
    - Ordered and furnished by qualified personnel; and
    - One that meets, but does not exceed, the beneficiary's medical need

For any service reported to Medicare, it is expected that the medical documentation clearly demonstrates that the service meets all of the above criteria. All documentation must be maintained in the patient's medical record and be available to the contractor upon request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® Number: SE1601 Revised

Article Release Date: May 7, 2019

Related CR Transmittal #: N/A

Related Change Request (CR) #: N/A

Effective Date: N/A

Implementation Date: N/A

Medicare Coverage for Chiropractic Services – Medical Record Documentation Requirements for Initial and Subsequent Visits

Note: CMS revised this article on May 7, 2019, to update sources of information regarding chiropractic services with additional references added to the Additional Information section of this article. We deleted resource references that are no longer available. All other information remains the same.

Provider Types Affected

This MLN Matters® Special Edition article is for doctors of chiropractic and other practitioners who submit claims to Medicare Administrative Contractors (MACs) for chiropractic services provided to Medicare beneficiaries.

This article is part of a series of Special Edition (SE) articles that the Centers for Medicare & Medicaid Services (CMS) prepared for doctors of chiropractic due to the request for educational materials at the September 24, 2015, Special Open Door Forum titled: "Improving Documentation of Chiropractic Services" and includes updated information. Other articles in the series are SE1602, which details the use of the AT modifier on chiropractic claims and SE1603, which identifies other useful resources to help doctors of chiropractic bill Medicare correctly for covered services.

Provider Action Needed

CMS is providing this SE article to help clarify CMS policy about Medicare coverage of chiropractic services for Medicare beneficiaries and documentation requirements for the beneficiary's initial visit and subsequent visits to the doctor of chiropractic. Know these policies along with any Local Coverage Determinations (LCDs) for these services in your

area that might limit circumstances under which Medicare pays for active/corrective chiropractic services.

Background

In 2018, the Comprehensive Error Testing Program (CERT) that measures improper payments in the Medicare Fee-For-Service (FFS) program reported a 41 percent error rate on claims for chiropractic services. Most of those errors were due to insufficient documentation or other documentation errors.

Medicare limits coverage of chiropractic services to treatment by means of manual manipulation (that is, by use of the hands) of the spine to correct a subluxation. The patient must require treatment by means of manual manipulation of the spine to correct a subluxation, and the manipulative services the doctor of chiropractic provides must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The doctor of chiropractic may use manual devices (that is, those that are hand-held with the thrust of the force of the device being controlled manually) in performing manual manipulation of the spine. However, Medicare makes no additional payment for use of the device, nor does Medicare recognize an extra charge for the device itself.

Doctors of chiropractic are limited to billing three Current Procedural Terminology (CPT) codes under Medicare: 98940 (chiropractic manipulative treatment; spinal, one to two regions), 98941 (three to four regions), and 98942 (five regions).When submitting manipulation claims, doctors of chiropractic must use an Acute Treatment (AT) modifier to identify services that are active/corrective treatment of an acute or chronic subluxation. The AT modifier, when used appropriately, should indicate expectation of functional improvement, regardless of the chronic nature or redundancy of the problem.

Documentation Requirements

The Social Security Act states that "no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period." See the Social Security Act (**section 1833(e)**).

In addition, the Medicare Benefit Policy Manual requires that the initial visit and all subsequent visits meet specific documentation requirements. See Chapter 15 (**section 240.1.2**).

Documentation Requirements for the Initial Visit

The following documentation requirements apply for initial visits whether the subluxation is demonstrated by x-ray or by physical examination:

1. History: The history the provider records in the patient record should include the following:

- Chief complaint including the symptoms causing patient to seek treatment
- Family history if relevant
- Past medical history (general health, prior illness, injuries, hospitalizations, medications; surgical history)

2. Present Illness: Description of the present illness including:

- Mechanism of trauma
- Quality and character of symptoms/problem
- Onset, duration, intensity, frequency, location, and radiation of symptoms
- Aggravating or relieving factors
- Prior interventions, treatments, medications, secondary complaints
- Symptoms causing patient to seek treatment

Note: Symptoms must be related to the level of the subluxation that the doctor of chiropractic cites. A statement on a claim that there is "pain" is insufficient. Describe the location of the pain and whether the vertebra you listed can produce pain in that area.

3. Physical Exam: Evaluation of musculoskeletal/nervous system through physical examination. If you demonstrate a subluxation you based on physical examination, two of the following four criteria (one of which must be asymmetry/misalignment or range of motion abnormality) are required and you need to document the criteria:

- **P - Pain/tenderness:** The perception of pain and tenderness is evaluated in terms of location, quality, and intensity. Most primary neuromusculoskeletal disorders manifest with a painful response. Pain and tenderness findings may be identified through one or more of the following: observation, percussion, palpation, provocation, and so forth. Furthermore, pain intensity may be assessed using one or more of the following; visual analog scales, algometers, pain questionnaires, and so forth.
- **A - Asymmetry/misalignment:** Asymmetry/misalignment may be identified on a sectional or segmental level through one or more of the following: observation (such as posture and heat analysis), static palpation for misalignment of vertebral segments, and/or diagnostic imaging.
- **R - Range of motion abnormality:** Changes in active, passive, and accessory joint movements may result in an increase or a decrease of sectional or segmental mobility. Range of motion abnormalities may be identified through one or more of the following: motion palpation, observation, stress diagnostic imaging, range of motion, and/or other measurement(s).
- **T -Tissue tone, texture, and temperature abnormality:** Changes in the characteristics of contiguous and associated soft tissue including skin, fascia, muscle, and ligament may be identified through one or more of the following procedures: observation, palpation, use of instrumentation, and/or test of length and/or strength.

Note: The P.A.R.T. (**P**ain/tenderness; **A**symmetry/misalignment; **R**ange of motion abnormality; and **T**issue tone, texture, and temperature abnormality) evaluation process is recommended as the examination alternative to the previously mandated demonstration of subluxation by x-ray/MRI/CT for services beginning January 1, 2000. The acronym P.A.R.T. identifies diagnostic criteria for spinal dysfunction (subluxation).

4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the bone named. The precise level of the subluxation must be specified by the doctor of chiropractic to substantiate a claim for manipulation of the spine. This designation is made in relation to the part of the spine in which the subluxation is identified as shown in the following table:

Area of Spine	Names of Vertebrae	Number of Vertebrae	Short Form or Other Name	Subluxation ICD-10 code
Neck	Occiput Cervical Atlas Axis	7	Occ, CO C1-C7 C1 C2	M99.00 M99.01
Back	Dorsal or Thoracic Costovertebral Costotransverse	12	D1-D12 T1-T12 R1-R12 R1-R12	M99.02
Low Back	Lumbar	5	L1-L5	M99.03
Pelvis	Ilii, R and L (I, Si)		I, Si	M99.05
Sacral	Sacrum, Coccyx		S, SC	M99.04

In addition to the vertebrae and pelvic bones listed, the Ilii (R and L) are included with the sacrum as an area where a condition may occur which would be appropriate for chiropractic manipulative treatment.

There are two ways you may specify the level of the subluxation in the patient's record.

- List the exact bones, for example: C5, C6, etc.
- The area may suffice if it implies only certain bones such as: occipito-atlantal (occiput and Cl (atlas)), lumbo-sacral (L5 and Sacrum) sacro-iliac (sacrum and ilium)

Following are some common examples of acceptable descriptive terms for the nature of the abnormalities:

- Off-centered
- Misalignment
- Malpositioning
- Spacing - abnormal, altered, decreased, increased
- Incomplete dislocation
- Rotation
- Listhesis - antero, postero, retro, lateral, spondylo
- Motion - limited, lost, restricted, flexion, extension, hypermobility, hypomotility, aberrant

You may use other terms. If they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable.

X-rays

As of January 1, 2000, Medicare does not require an x-ray to demonstrate the subluxation. However, you may use an x-ray for this purpose if you so choose.

The date of the x-ray must be reasonably close to (within 12 months prior or 3 months following) the beginning of treatment. In certain cases of chronic subluxation (for example, scoliosis), an older x-ray may be accepted if the beneficiary's health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the condition is permanent.

A previous CT scan and/or MRI are acceptable evidence if a subluxation of the spine is demonstrated.

5. Treatment Plan: The treatment plan should include the following:

- Recommended level of care (duration and frequency of visits)
- Specific treatment goals
- Objective measures to evaluate treatment effectiveness

Date of the initial treatment.

The patient's medical record.

- Validate all the information on the face of the claim, including the patient's reported diagnosis(s), physician work (CPT code), and modifiers.
- Verify that all Medicare benefit and medical necessity requirements were met.

Documentation Requirements for Subsequent Visits

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. **History**
   a. Review of chief complaint
   b. Changes since last visit
   c. Systems review if relevant
2. **Physical examination**
   a. Examination of area of spine involved in diagnosis
   b. Assessment of change in patient condition since last visit
   c. Evaluation of treatment effectiveness
3. **Documentation of treatment given on day of visit.**

Necessity for Treatment of Acute and Chronic Subluxation

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function.

The patient must have a subluxation of the spine as demonstrated by x-ray or physical examination, as described above.

Most spinal joint problems fall into the following categories:

- **Acute subluxation**-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical examination as specified above. The result of chiropractic manipulation is expected to be an improvement in, or arrest of progression, of the patient's condition.
- **Chronic subluxation**-A patient's condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as is the case with an acute condition); however, the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

You must place the HCPCS modifier AT on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However, the presence of the HCPCS modifier AT may not in all instances indicate that the service is reasonable and necessary.

As shown in the Medicare Benefit Policy Manual, Chapter 15, Section 240, the doctor of chiropractic should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (for example, strains or sprains) problems may require as many as three months of treatment but some require very little treatment. In the first several days,

treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already "set" and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

ICD-10 Codes that Support Medical Necessity for Chiropractic Services

The chiropractic LCDs for MACs include ICD-10 Coding Information for ICD-10 Codes that support the medical necessity for chiropractic services. There may be additional documentation information in your LCD. There are links to the chiropractic LCDs in MLN Matters SE article SE1603.

The **Group 1 (primary) codes** are the only covered ICD-10-CM codes that support medical necessity for chiropractic services.

- Primary: ICD-10-CM Codes (Names of Vertebrae)
- List the precise level of subluxation as the primary diagnosis.

The Groups 2, 3, and 4 ICD-10-CM codes support the medical necessity for diagnoses and involve short, moderate, and long-term treatment:

- **Group 2 Codes**: Category I - ICD-10-CM Diagnosis (diagnoses that generally require **short term treatment**)
- **Group 3 Codes**: Category II - ICD-10-CM Diagnosis (diagnoses that generally require **moderate term treatment**)
- **Group 4 Codes**: Category III - ICD-10-CM Diagnosis (diagnoses that may require **long term treatment**)

ICD-10 Codes that DO NOT Support Medical Necessity are **all** ICD-10-CM codes **not** listed in LCDs under *ICD-10-CM Codes That Support Medical Necessity*.

Additional Information

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

A new Medicare Learning Network Educational Tool, Medicare Documentation Job Aid For Doctors of Chiropractic, is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/MLN1232664.html.

The Medicare Benefit Policy Manual, Chapter 15, Section 240 is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf.

The CERT 2018 Medicare Fee-For-Service Supplemental Improper Payment Data report is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2018MedicareFFSSuplementalImproperPaymentData.pdf.

Article SE1101, Overview of Medicare Policy Regarding Chiropractic Services, is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1101.pdf.

Article MM3449, Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy, Full Replacement of CR3063 is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm3449.pdf.

Article SE0749, Addressing Misinformation Regarding Chiropractic Services and Medicare, is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0749.pdf.

Other articles in this series on chiropractic services include SE1602, which is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/se1602.pdf. SE1602 discusses the use of the AT modifier. Also, SE1603 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/se1603.pdf lists a wide array of other materials to assist doctors of chiropractic in delivering covered services to Medicare beneficiaries and correctly billing for those services.

Document History

- May 7, 2019 - CMS revised this article to update sources of information regarding chiropractic services with additional references added to the Additional Information section of this article. We deleted resource references that are no longer available. All other information remains the same.
- June 18, 2018 – We revised the article to delete the word “always” from the line for item 5 (Treatment Plan) on page 5. All other information remains the same.
- March 16, 2016 – Initial article released.

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Chiropractic Services

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

Number: 0107

Table Of Contents

Policy History

Last Review
04/09/2024
Effective: 03/25/1995
Next Review: 01/23/2025

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes

Policy

Scope of Policy

This Clinical Policy Bulletin addresses chiropractic services.

I. Medical Necessity

A. Aetna considers chiropractic services medically necessary when *all* of the following criteria are met:

1. The member has a neuromusculoskeletal disorder; *and*
2. The medical necessity for treatment is clearly documented; *and*

3. Improvement is documented within the initial 2 weeks of chiropractic care.

If no improvement is documented within the initial 2 weeks, additional chiropractic treatment is considered not medically necessary unless the chiropractic treatment is modified.

If no improvement is documented within 30 days despite modification of chiropractic treatment, continued chiropractic treatment is considered *not* medically necessary.

Once the maximum therapeutic benefit has been achieved, continuing chiropractic care is considered not medically necessary.

B. Home-based chiropractic service is considered medically necessary in selected cases based upon the member's needs (i.e., the member must be homebound). This may be considered medically necessary in the transition of the member from hospital to home, and may be an extension of case management services.
C. Chiropractic manipulation in asymptomatic persons or in persons without an identifiable clinical condition is considered not medically necessary.
D. Chiropractic care in persons, whose condition is neither regressing nor improving, is considered not medically necessary.
Chiropractic manipulation has no proven value for treatment of idiopathic scoliosis or for treatment of scoliosis beyond early adolescence, unless the member is exhibiting pain or spasm, or some other medically necessary indications for chiropractic manipulation are present.

II. **Experimental, Investigational, or Unproven**

A. Aetna considers the following procedures experimental, investigational, or Unproven:

1. *Manipulation when it is rendered for non-neuromusculoskeletal conditions (see examples below, not an all-inclusive list):*

    - Attention-deficit hyperactivity disorder
    - Asthma
    - Autism spectrum disorder
    - Depression
    - Dizziness / vertigo
    - Dysmenorrhea
    - Epilepsy
    - Female infertility
    - Gastro-intestinal disorders
    - Improvement of brain function
    - Menopause-associated vasomotor symptoms
    - Prevention of falls
    - Treatment of post-concussion syndrome;

2. *Manipulation of infants for non-neuromusculoskeletal indications (see examples below, not an all-inclusive list):*

    - Infants with gastro-intestinal disorders including constipation
    - Excessive intestinal gas
    - Gastroesophageal reflux disease;

3. *Chiropractic procedures:*

    - Active Release Technique (see CPB 0388 - Complementary and Alternative Medicine (../300_399/0388.html))
    - Active Therapeutic Movement (ATM2)
    - Advanced Biostructural Correction (ABC) Chiropractic Technique
    - Applied Spinal Biomechanical Engineering
    - Atlas Orthogonal Technique
    - Bioenergetic Synchronization Technique
    - Biogeometric Integration
    - Blair Technique

- Bowen Technique
- Chiropractic Biophysics Technique / Chiropractic BioPhysics Methods
- Coccygeal Meningeal Stress Fixation Technique
- ConnecTX (an instrument-assisted connective tissue therapy program)
- Cox decompression manipulation/technique
- Cranial Manipulation
- Directional Non-Force Technique
- FAKTR (Functional and Kinetic Treatment with Rehab) Approach
- Gonzalez Rehabilitation Technique
- Inertial traction (inertial extensilizer decompression table
- IntraDiscNutrosis program
- Koren Specific Technique
- Manipulation for infant colic
- Manipulation for internal (non-neuromusculoskeletal) disorders (Applied Kinesiology)
- Manipulation Under Anesthesia (see CPB 0204 - Manipulation Under General Anesthesia (../200_299/0204.html))
- Moire Contourographic Analysis
- Network Technique
- Neural Organizational Technique
- Neuro Emotional Technique
- NUCCA (National Upper Cervical Chiropractic Association) procedure
- Origin insertion release technique
- Positional release therapy
- Sacro-Occipital Technique
- Spinal Adjusting Devices (Activator, ProAdjuster, PulStarFRAS, Ultralign adjusting device)
- Therapeutic (Wobble) Chair
- Upledger Technique and Cranio-Sacral Therapy
- Webster Technique (for breech babies)
- Whitcomb Technique (see CPB 0388 - Complementary and Alternative Medicine (../300_399/0388.html));

4. *Diagnostic procedures:*

- Computerized radiographic mensuration analysis for assessing spinal mal-alignment
- Dynamic spinal visualization (including digital motion x-ray and videofluoroscopy, also known as cineradiography)
- Neurocalometer/Nervoscope (see CPB 0029 - Thermography (../1_99/0029.html))
- Para-spinal electromyography (EMG) / Surface scanning EMG (see CPB 0112 - Surface Scanning and Macro Electromyography (0112.html))
- Spinoscopy (see CPB 0112 - Surface Scanning and Macro Electromyography (0112.html))
- Thermography (see CPB 0029 - Thermography (../1_99/0029.html)).

III. **Policy Limitations and Exclusions**

Note: Some plans have limitations or exclusions applicable to chiropractic care. Please check benefit plan descriptions for details.

IV. **Related Policies**

- CPB 0029 - Thermography (../1_99/0029.html)
- CPB 0112 - Surface Scanning and Macro Electromyography (0112.html)
- CPB 0204 - Manipulation Under General Anesthesia (../200_299/0204.html)
- CPB 0388 - Complementary and Alternative Medicine (../300_399/0388.html)

CPT Codes / HCPCS Codes / ICD-10 Codes

CPT codes covered if selection criteria are met:

Code	Code Description
98940	Chiropractic manipulative treatment (CMT); spinal, one to two regions
98941	spinal, three to four regions
98942	spinal, five regions
98943	extraspinal, one or more regions
CPT codes not covered for indications listed in the CPB:	
ConnecTX, inertial traction, positional release therapy, IntraDiscNutrosis program, Origin insertion release technique, Ultralign adjusting device - no specific code:	
22505	Manipulation of spine requiring anesthesia, any region
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes [not covered for FAKTR]
Other CPT codes related to the CPB:	
20552	Injection(s); single or multiple trigger point(s), one or two muscle(s)
20553	single or multiple trigger point(s), three or more muscle(s)
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	3 or more muscles
95836 - 95857	Muscle and range of motion testing
95860 - 95887	Electromyography and nerve conduction tests
95907 - 95913	Nerve conduction studies
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method
96000 - 96004	Motion analysis
97010 - 97799	Physical medicine and rehabilitation
HCPCS codes covered if selection criteria are met:	
Home-based chiropractic service - no specific code	

Code	Code Description
Other HCPCS codes related to the CPB:	
G0151	Services performed by a qualified physical therapist in the home health or hospice setting, each 15 minutes
S3900	Surface electromyography (EMG)
S9131	Physical therapy; in the home, per diem
ICD-10 codes covered if selection criteria are met (0-3 years of age):	
G24.3	Spasmodic torticollis
G54.0 - G55	Nerve root and plexus disorders
G71.0 - G72.9	Primary disorders of muscles and other myopthies
G80.0 - G80.9	Cerebral palsy
M05.00 - M08.99	Rheumatoid arthritis and other inflammatory polyarthropathies
M40.00 - M40.51, M42.00 - M54.9	Deforming dorsopathies, spondylitis and other dorsopathies [excluding scoliosis]
M91.10 - M94.9	Chondropathies
Q65.00 - Q68.8	Congenital musculoskeletal deformities
Q72.70 - Q72.73, Q74.1 - Q74.2	Congenital malformations of lower limb, including pelvic girdle
Q74.0, Q74.9, Q87.89	Congenital malformations of upper limb, including shoulder girdle
Q76.0 - Q76.49	Congenital malformations of spine
Q77.0 -Q77.1 Q77.4 - Q77.5 Q77.7 - Q77.9 Q78.9	Osteochrondrodysplasia
S03.4xx+	Sprain of jaw

Code	Code Description
S13.0xx+ - S13.9xx+, S23.0xx+ - S23.9xx+, S33.0xx+ - S33.9xx+, S43.001+ - S43.92X+, S53.001+ - S53.499, S63.001+ - S63.92X+, S73.001+ - S73.199+, S83.001 - S83.92X+, S93.01X+ - S93.699+	Dislocation and sprains of joint and ligaments
S14.2xx+ - S14.9xx+, S24.2xx+ - S24.9XX+, S34.21x+ - S34.9XX+	Injury to nerve roots, spinal plexus and other nerves
S16.1xx+	Strain of muscle, fascia and tendon at neck level
S23.41x+ - S23.429+, S33.4xx+ S33.8xx+ - S33.9xx+	Sprain of other ribs, sternum, and pelvis
S39.002+, S39.012+, S39.092+	Injury or strain of muscle, fascia and tendon of lower back
S44.00x+ - S44.92x+	Injury of nerves at shoulder and upper arm level

Code	Code Description
S46.011+ - S46.019+, S46.111+ - S46.119+, S46.211+ - S46.219+, S46.311+ - S46.319+, S46.811+ - S46.819+, S46.911+ - S46.919+	Injury of muscle, fascia and tendon at shoulder and upper arm level
S74.00x+ - S74.92x+	Injury of nerves at hip and thigh level
S76.011+ - S76.019+, S76.111+ - S76.119+, S76.211+ - S76.219+, S76.311+ - S76.319+, S76.811+ - S76.819+, S76.911+ - S76.919+	Injury and strain of muscle, fascia and tendon at hip and thigh level
S84.00x+ - S84.92x+	Injury of nerves at lower leg level

Code	Code Description
S86.001+ - S86.019+, S86.111+ - S86.119+, S86.211+ - S86.219+, S86.311+ - S86.319+, S86.811+ - S86.819+, S86.911+ - S86.919+	Injury of muscle, fascia and tendon at lower leg level
S94.00x+ - S94.92x+	Injury of nerves at ankle and foot level
S96.001+ - S96.019+, S96.111+ - S96.119+, S96.211+ - S96.219+, S96.811+ - S96.819+, S96.911+ - S96.919+	Injury of muscle, fascia and tendon at ankle and foot level
ICD-10 codes covered if selection criteria are met for adults and children (4 years of age and older):	
G24.3	Spasmodic torticollis
G43.001 - G43.919	Migraine
G44.001 - G44.89	Tension and other headaches
G54.0 - G55	Nerve root and plexus disorders
G56.00 - G56.93	Mononeuritis of upper limb
G57.00 - G59	Mononeuritis of lower limb

Code	Code Description
G71.00 - G72.9	Muscular dystrophies and other myopathies
G80.0 - G80.9	Cerebral palsy
M05.00 - M08.99	Rheumatoid arthritis and other inflammatory polyarthropathies
M12.00 - M13.89	Other and unspecified arthropathies
M15.0 - M19.93	Osteoarthritis and allied disorders
M20.001 - M25.9	Other joint disorders
M26.601 - M26.69	Temporomandibular joint disorders
M35.3, M75.00 - M79.9	Rheumatism, shoulder lesions and enthesopathies [excludes back]
M40.00 - M40.51, M42.00 - M54.9	Deforming dorsopathies, spondylitis and other dorsopathies [excluding scoliosis]
M85.30 - M85.39	Osteitis condensans
M89.00 - M89.09	Algoneurodystrophy
M91.10 - M94.9	Osteochondropathies
M95.3	Acquired deformity of neck
M95.5	Acquired deformity of pelvis
M95.8	Other specified acquired deformities of musculoskeletal system
M95.9	Acquired deformities of musculoskeletal system, unspecified
M99.00 - M99.09	Segmental and somatic dysfunction [allowed by CMS]

Code	Code Description
M99.10 - M99.19	Subluxation complex (vertebral)
M99.83 - M99.84	Other acquired deformity of back or spine
Numerous options	Other, multiple, and ill-defined dislocations [including vertebra]
Q65.00 - Q68.8	Congenital musculoskeletal deformities
Q74.1 - Q74.2	Congenital malformations of lower limb, including pelvic girdle
Q74.0, Q74.9, Q87.89	Congenital malformations of upper limb, including shoulder girdle
Q76.0 - Q76.49	Congenital malformations of spine
Q77.0 -Q77.1 Q77.4 - Q77.5 Q77.7 - Q77.9 Q78.9	Osteochrondrodysplasia
R51	Headache
S03.40x+ - S03.42x+	Sprain of jaw

Code	Code Description
S13.0xx+ - S13.9xx+, S23.0xx+ - S23.9xx+, S33.0xx+ - S33.9xx+, S43.001+ - S43.92X+, S53.001+ - S53.499, S63.001+ - S63.92X+, S73.001+ - S73.199+, S83.001 - S83.92X+, S93.01X+ - S93.699+	Dislocation and sprains of joints and ligaments
S14.2xx+ - S14.9xx+, S24.2xx+ - S24.9XX+ S34.21x+ - S34.9xx+	Injuries to nerve root(s), spinal plexus(es) and other nerves
S16.1xx+	Strain of muscle, fascia and tendon at neck level
S23.41x+ - S23.429+, S33.4xx+ S33.8xx+ - S33.9xx+	Sprain of other ribs, sternum, and pelvis
S39.002+, S39.012+, S39.092+	Injury or strain of muscle, fascia and tendon of lower back
S44.00x+ - S44.92x+	Injury of nerves at shoulder and upper arm level

Code	Code Description
S46.011+ - S46.019+, S46.111+ - S46.119+, S46.211+ - S46.219+, S46.311+ - S46.319+, S46.811+ - S46.819+, S46.911+ - S46.919+	Injury of muscle, fascia and tendon at shoulder and upper arm level
S74.00x+ - S74.92x+	Injury of nerves at hip and thigh level
S76.011+ - S76.019+, S76.111+ - S76.119+, S76.211+ - S76.219+, S76.311+ - S76.319+, S76.811+ - S76.819+, S76.911+ - S76.919+	Injury and strain of muscle, fascia and tendon at hip and thigh level
S84.00x+ - S84.92x+	Injury of nerves at lower leg level

Code	Code Description
S86.001+ - S86.019+, S86.111+ - S86.119+, S86.211+ - S86.219+, S86.311+ - S86.319+, S86.811+ - S86.819+, S86.911+ - S86.919+	Injury of muscle, fascia and tendon at lower leg level
S94.011+ - S94.019+, S94.111+ - S94.119+, S94.211+ - S94.219+, S94.311+ - S94.319+, S94.811+ - S94.819+, S94.911+ - S94.919+	Injury of nerves at ankle and foot level
S96.001+ - S96.019+, S96.111+ - S96.119+, S96.211+ - S96.219+, S96.811+ - S96.819+, S96.911+ - S96.919+	Injury of muscle, fascia and tendon at ankle and foot level
ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):	
F07.81	Postconcussional syndrome

Code	Code Description
F32.0 - F32.9	Major depressive disorder, single episode
F33.0 - F33.9	Major depressive disorder, recurrent
F84.0 - F84.9	Pervasive developmental disorder
F90.0 - F90.9	Attention deficit hyperactivity disorder
G40.001 - G40.919	Epilepsy and recurrent seizures
H81.01 - H81.49	Vertigo
J45.20 - J45.998	Asthma
K00.0 - K95.89	Diseases of the digestive system
M41.00 - M41.9	Scoliosis [and kyphoscoliosis], idiopathic; resolving infantile idiopathic scoliosis; and progressive infantile idiopathic scoliosis
N94.4 - N94.6	Dysmenorrhea
N95.1	Menopausal and female climacteric states [not covered for menopause-associated vasomotor symptoms]
N97.0 - N97.9	Female infertility
O32.1xx0 - O32.1xx9	Maternal care for breech presentation
R10.83	Colic
R42	Dizziness and giddiness
R56.1	Post traumatic seizures
R56.9	Unspecified convulsions [seizure disorder NOS]
Z91.81	History of falling

Background

Chiropractic is a branch of the healing arts that is concerned with human health and prevention of disease, and the relationship between the neuroskeletal and musculoskeletal structures and functions of the body. The primary focus of chiropractic is the relationship of the spinal column and the nervous system, as it relates to the restoration and maintenance of health. A practitioner of chiropractic is referred to as Doctor of Chiropractic (D.C.), Chiropractic Physician or Chiropractor.

The primary focus of the profession is the vertebral column; however, all other peripheral articular structures and adjacent tissues may be treated, depending on state chiropractic scope of practice laws.

Neuromusculoskeletal conditions commonly treated by chiropractic physicians include:

- Contractures
- Degenerative conditions of the joints
- Fibrositis
- Headaches (including tension headaches, migraines, and vertebrogenic-type headaches)
- Myalgia
- Myofibrositis
- Neuralgias
- Non-infectious inflammatory disorders of the joints, muscles, and ligaments of the spine and extremities
- Osteoarthritis – Intervertebral disc disorders of the spine such as disc protrusion, bulging, degeneration, and displacement
- Peripheral joint trauma
- Radiculopathies
- Repetitive motion injuries
- Spinal facet syndromes
- Spondylolisthesis
- Spondylosis
- Sprains and strains.

The chiropractor may treat multiple neuromusculoskeletal conditions during a single visit.

Chiropractors use broadly accepted diagnostic procedures to assess diseases and adverse health conditions.

The primary mode of chiropractic treatment is manipulation or adjustment. Chiropractic manipulation is the application of a controlled force to re-establish normal articular function. The objective of manipulation is to restore the normal mobility and range of motion within the joint.

The chiropractor affects the body's physiology and promotes healing by locating and correcting mechanical disorders of joints or joint subluxations. In chiropractic, the term "subluxation" is used interchangeably with the term "spinal subluxation complex" or "vertebral subluxation complex". A subluxation may also be called a joint dysfunction, joint fixation, functional joint lesion, somatic dysfunction, or biomechanical dysfunction. A subluxation has been defined as a fixation, lack of motion, or aberrant motion of an articular joint, resulting in physiological changes within the joint that may cause inflammation of the joint and its capsule, which may result in pain, swelling, muscle spasm, nerve irritation, damage to joint cartilage, and loss of normal range of motion. Nerve irritation may cause pain and spasm to radiate. Vascular, sensory, and motor changes may accompany a spinal subluxation complex.

Some non-neuromusculoskeletal conditions may be managed by chiropractors when practicing within the scope of their licenses. In assessing the need for chiropractic treatment, both neuromusculoskeletal conditions and any related coexisting non-neuromusculoskeletal disorders should be considered.

Chiropractors treat disease without the use of medications or surgery. When medication or surgery is indicated, the chiropractor should refer the patient to an allopathic or osteopathic physician, as appropriate. Patients may receive medical treatment from an allopathic or osteopathic physician simultaneously or in conjunction with a chiropractic physician.

Chiropractors may diagnose disease and prescribe office-based treatments and home exercises. Chiropractors do not commonly make house calls.

In addition to manipulation, chiropractors may employ adjunctive nutritional, hygienic, and environmental modalities, physiotherapeutic modalities, rehabilitation, and therapeutic massage for the treatment of subluxation and related conditions. The use of adjunctive modalities must be appropriate for the diagnosis and must augment or enhance the manipulative treatment. The type of therapy used should be consistent with the status of the patient's condition (e.g., acute, subacute, rehabilitative or chronic).

Examples of adjunctive physiotherapeutic measures that have been used in chiropractic include:

- Acute phase: thermal (cold) therapy, electrotherapy, trigger point therapy;
- Rehabilitative phase: exercise; and
- Subacute phase: thermal (heat), electrotherapy, ultrasound.

Massage therapy and traction procedures are not considered to be manipulation.

Literature indicates that chiropractic treatment during pregnancy may be appropriate. Chiropractic therapy is often effective in reducing back pain and allowing the pregnant patient to function and perform her activities of daily living.

Physical Therapy Modalities

Although chiropractors often use physical modalities with spinal manipulation, there is a lack of evidence that modalities yield additional benefits over spinal manipulation alone. The UCLA Back Pain Study examined the net effect of physical modalities on low back pain outcomes among chiropractic patients in a managed-care setting (Hurwitz et al, 2002; Hurwitz et al, 2006). Half of the 681 patients participating in this clinical trial of low back pain treatment strategies were randomized to chiropractic care with physical modalities (n = 172) or without physical modalities (n = 169). The other half of the study subjects were assigned to medical care with or without physical therapy modalities. Subjects were followed for 6 months with assessments at 2, 4, and 6 weeks and at 6 months. The primary outcome variables were average and most

severe low back pain intensity in the past week, assessed with numerical rating scales (0 to 10), and low back-related disability, assessed with the 24-item Roland-Morris Disability Questionnaire. Almost 60 % of the subjects had baseline low back pain episodes of more than 3 months' duration. The 6-month follow-up was 96 %. The investigators reported, comparing groups assigned to chiropractic alone to chiropractic plus physical therapy modalities, the adjusted mean differences between groups in improvements in average and most severe pain and disability were clinically insignificant at all follow-up assessments (Hurwitz et al, 2002). The investigators reported that clinically relevant improvements in average pain and disability were more likely in the modalities group at 2 and 6 weeks, but this apparent advantage disappeared at 6 months. Perceived treatment effectiveness was greater in the modalities group. The investigators concluded that physical modalities used by chiropractors in this study did not appear to be effective in the treatment of patients with low back pain, although the investigators noted that a small short-term benefit for some patients cannot be ruled out. In a subsequent report on the 18-month outcomes of the UCLA Back Pain Study, 89.6 % of the original cohort were followed through 18 months (Hurwitz et al, 2006). Among study subjects assigned to chiropractic care, assignment to physical therapy modalities in addition to chiropractic was not associated with improvement or remission (adjusted RR = 0.98; 95 % confidence interval [CI]: 0.62 to 1.55) compared to chiropractic care alone. The investigators concluded that physical modalities appear to have no benefit in chiropractic care.

In another publication, Haas et al (2004) reported on a randomized controlled pilot study conducted in the faculty practice of a chiropractic college outpatient clinic examining the effects of the number of chiropractic treatment visits for manipulation with and without physical modalities on chronic low back pain and disability. The study involved 72 patients with chronic, non-specific low back pain of mechanical origin. All patients received high-velocity low-amplitude spinal manipulation. Half received one or two of the following physical therapy modalities at each visit: soft tissue therapy, hot packs, electrotherapy or ultrasound. The investigators reported that, at 4 weeks, there was no effect of treatment regimen (chiropractic or chiropractic plus physical therapy modalities) on pain or functional disability at 4 weeks or 12 weeks follow-up.

In another randomized controlled clinical study, joint manipulation plus myofascial therapy was found to be no more effective than joint manipulation alone for persons with subacute low back pain. Hsieh et al (2002) reported on the results of a randomized, assessor-blinded clinical trial to investigate the relative effectiveness of 3 manual treatments and back school for patients with subacute low back pain. Two hundred patients with subacute low back pain were randomly assigned to one of four treatments for 3 weeks: back school, joint manipulation, myofascial therapy, and combined joint manipulation and myofascial therapy. The investigators reported that all 4 groups showed significant improvement in pain and activity scores after 3 weeks of care, but did not show further significant improvement at the 6-month follow-up assessment. No statistically significant differences were found among treatment groups at either at the 3-week or 6-month reassessments. The investigators concluded that, for subacute low back pain, combined joint manipulation and myofascial therapy was no more effective than joint manipulation or myofascial therapy alone.

Experimental, Investigational, or Unproven Interventions

Some diagnostic and therapeutic procedures are not considered medically necessary or essential to the treatment of an illness or injury and are not broadly accepted by the chiropractic profession.

Manipulation is deemed experimental, investigational, or unproven when it is rendered for non-neuromusculoskeletal conditions, because the effectiveness of chiropractic manipulation for this indication has not been proven by adequate scientific studies, published in peer-reviewed scientific journals. An example is the use of manipulation in lieu of antibiotics for treatment of suppurative otitis media. Manipulative procedures are not proven to be an effective substitute for childhood immunizations or for the treatment of infectious diseases, and are not covered for these indications.

Chiropractic/manipulative management of scoliosis has not been shown to substantially alter the idiopathic scoliotic curve or progression of the curve in late adolescence or adulthood. Therefore, chiropractic manipulation is considered unproven and is not covered for treatment of idiopathic scoliosis or for treatment of scoliosis beyond early

adolescence, unless the patient is exhibiting pain or spasm or if some other medically necessary indication for chiropractic manipulation is present.

Scoliotic deviations may be a result of functional adaptations to lumbo-pelvic lower extremity dysfunction for which chiropractic care is appropriate. Manipulative procedures, in conjunction with electrical muscle stimulation and exercise, can significantly reduce the associated muscle spasm and resultant pain of scoliosis during the acute exacerbations and/or injury, and improve spinal mobility prior to an active exercise regimen. Chiropractic/manipulative management of scoliosis, however, has not been shown to substantially alter the idiopathic scoliotic curve or progression of the curve in late adolescence or adulthood. In a systematic literature review of non-surgical treatment in adult scoliosis, Everett and Patel (2007) stated that there is only very weak evidence for the use of chiropractic manipulation in adult deformity.

The use of chiropractic to correct abnormal spinal curvature in asymptomatic persons is considered experimental, investigational, or unproven. Chiropractic Biophysics Technique (CPB), also known as Clinical Biomechanics of Posture, is a variation of straight (subluxation-based) chiropractic whose overall goal is to restore posture. Advocates of CBP are reported to ascribe to the controversial position that decreased neck curvature is pathological and requires correction whether or not the patient has symptoms.

The CBP method is based on the idea that postural analysis is valid for diagnosing ligament contractures, muscle weakness, and proprioceptive deficits. The assumed deficits supposedly reduce blood flow, which decreases oxygen delivery and causes various diseases. To qualify for treatment, patients undergo a postural examination and are screened for contraindications to manipulation and cervical extension traction. Therapy begins with relief care consisting of 1 to 12 sessions of spinal adjustments, cold or hot packs, trigger point therapy for muscle spasms, and/or massage with a motorized table. When relief care ends, CBP practitioners switch patients to rehabilitative care, which consists of weekly mirror image adjustments, neck and low back extension traction,

as well as mirror image exercises intended to modify spinal curvature over a longer period of time. Initial rehabilitative plans often last 6 to 12 months, after which patients are switched to monthly visits for life.

There is insufficient scientific evidence to support the use of CBP. The published peer reviewed literature focuses primarily on explaining the theoretical basis for the Chiropractic Biophysics Technique. Harrison et al (1996) discussed the theory underlying the Chiropractic Biophysics Technique, explaining how certain linear algebra concepts provide the theoretical basis for making postural corrections. The authors explained how Chiropractic Biophysics Technique uses these concepts in examination procedures, manual spinal manipulation, instrument assisted spinal manipulation, postural exercises, extension traction and clinical outcome measures. Jackson et al (1993) reported on the intra- and inter-rater reliability of the geometric line drawings used in CBP on lateral cervical radiographs. The investigators concluded that the reliabilities for intra- and inter-examiner were accurate enough to provide measurements for future clinical studies.

There is a paucity of published peer reviewed literature evaluating the effectiveness of the Chiropractic Biophysics Technique in improving clinical outcomes (e.g., reductions in pain and disability, improvements in function). Colloca and Polkinghorn (2003) described the use of CBP protocols in conjunction with other chiropractic techniques in 2 persons with Ehlers-Danlos syndrome. In a 10-year follow-up study of neck x-ray findings in asymptomatic patients, Gore (2001) found no relationship between the loss of neck curvature and the development of pain or degenerative changes. Haas and colleagues (1999) noted that changes in spinal structure do not necessarily cause symptoms. They stated that CBP advocates have failed to

(i) establish the biological plausibility of what they consider an ideal spine, (ii) show that their diagnostic tests enable better patient management, (iii) demonstrate meaningful outcomes such as decreased pain or disability, and (iv) validate the routine use of spinal x-rays to measure spinal displacement. Active release technique (ART) is a patented soft tissue system that treats problems with muscles, tendons, ligaments, fascia and nerves (e.g., headaches, back pain, carpal

tunnel syndrome, shin splints, shoulder pain, sciatica, plantar fasciitis, knee problems, and tennis elbow). These conditions have one important commonality – they often result from injury to over-used muscles. Each ART session is a combination of examination and treatment. The ART provider uses his/her hands to evaluate the texture, tightness and movement of muscles, fascia, tendons, ligaments and nerves. Abnormal tissues are treated by combining precisely directed tension with very specific patient movements. These treatment protocols – over 500 specific moves – are unique to ART. They supposedly allow providers to identify and correct the specific problems that are affecting each individual patient. Active release technique is similar to some massage techniques, albeit more aggressive.

While ART may be utilized by some chiropractors, it is different from conventional chiropractic manipulation. Furthermore, Drover et al (2004) reported that ART protocols did not reduce inhibition or increase strength in the quadriceps muscles of athletes with anterior knee pain. Further study is required.

There is inadequate evidence of the effectiveness of spinal manipulation in treatment of dysmenorrhea. In a Cochrane review, Proctor et al (2006) concluded that there is no evidence to suggest that spinal manipulation is effective in the treatment of primary and secondary dysmenorrhea.

There is inadequate evidence of the effectiveness of chiropractic for treatment of epilepsy. In a review on the use of complementary and alternative medicine (CAM) including manipulative-based medicine such as chiropractic in the treatment of epilepsy, Ricotti and Delanty (2006) noted that in the available literature, there is a sense of the merit of these therapies in epilepsy, but there is a paucity of research in these areas. The authors stated that, in a science of double-blind, randomized controlled trials, appropriate designs and outcome measurements need to be tailored to CAM. More effort needs to be put into future trials, with the assistance of qualified CAM professionals to ensure conformation to their therapeutic principles.

The ProAdjuster is a hand-held device most commonly used by chiropractors for the diagnosis and treatment of back pain. The technology associated with this device entails the use of a piezoelectric

sensing head/probe that is pressed onto the spine sending ultrasound to the vertebral column for measurements of movement of each vertebra or the lack of it. A series of signal waves, each representing an individual vertebra, appears on a computer screen beside digital bar charts, where longer, red bars indicate a mis-alignment in the lower spine. When the ProAdjuster identifies a problem, it then delivers a series of rapid and measured percussion taps that works like a traditional chiropractic adjustment. The sensing system will automatically stop the adjustment when normal motion is detected.

There is insufficient scientific evidence regarding the clinical value of the ProAdjuster for the management of patients with back pain or any other conditions. Available published literature centers on the piezoelectric sensor technology. According to Zhang and Fu (2004), piezoelectric quartz crystal biosensor is a new sensor with the comprehensive utilization of the high sensitivity to mass and the surface characteristics of quartz crystal (e.g., conductance, density, dielectric constant, viscosity), as well as the high specificity of biologic identification molecules. The authors state that piezoelectric quartz crystal biosensors have been used in various settings such as environmental monitoring (e.g., detection of organophosphate levels in river water), foods sanitary control (e.g., detection of sulfamethoxazole residue or Salmonella in milk), as well as medical laboratory diagnosis (e.g., DNA biosensor, biosensor for estrogenic substances, and micro-array immunosensor for quantitative detection of serum or urine human chorionic gonadotropin).

Beck and colleagues (2006) compared a piezoelectric contact sensor with an accelerometer for measuring the mechanomyographic (MMG) signal from the biceps brachii during sub-maximal to maximal isokinetic and isometric forearm flexion muscle actions. These researchers found that there were no significant relationships for normalized MMG mean power frequency (MPF, percent maximum) versus isokinetic and isometric torque for the contact sensor, but the accelerometer demonstrated a quadratic or linear relationship for the isokinetic and isometric muscle actions, respectively. There were also a number of significant mean differences between the contact sensor and accelerometer for normalized MMG amplitude or MPF values. The findings of this study indicated that in some cases involving dynamic and isometric muscle actions, the

contact sensor and accelerometer resulted in different torque-related responses that may affect the interpretation of the motor control strategies involved.

A number of other spinal adjusting instruments have been developed that share similarities to the ProAdjuster, including the PulStarFRAS. Similar to the ProAdjuster, the PulStarFRAS (Function Recording and Analysis System) can be used for diagnostic as well as therapeutic purposes. The PulStarFRAS is designed to generate an objective and repeatable analysis of the mobility (compliance) of the spinal structure. The resulting computerized differential compliance (CDC) scans are used as an aid in the identification of spinal joint dysfunction. The PulStarFRAS provides a low-force multiple impulse therapy to resolve joint fixation. There is a lack of adequate evidence regarding its clinical value of the PulStarFRAS.

The Activator is a spinal adjusting instrument that is similar to the ProAdjuster in that it provides low force. The Activator Methods Chiropractic Technique system of analysis isolates and locates euronro-articular dysfunctions or subluxations by observing changes in relative leg length while the patient lies prone on a treatment table. The Activator Adjusting Instrument is applied based on indications from the analysis as to somatic location and force vector. The Activator produces a maximum of 0.3 Joules of kinetic energy, which is intended to be sufficient to induce relative movement of vertebrae and their associated joints, but below the forces associated with tissue injury.

There is insufficient evidence to validate the clinical validity of the Activator Methods Chiropractic Technique methods of leg length analysis. In addition, there is insufficient evidence that use of the Activator results in benefits equivalent to the more studied methods of manual chiropractic manipulation.

A study by Wood et al (2001) is a controlled clinical outcome study comparing the Activator technique to manual manipulation. In a pilot study (n = 30), Wood et al (2001) found that both instrumental manipulation by means of the Activator II Adjusting Instrument and manual manipulation have beneficial effects associated with reducing pain and disability and improving cervical range of motion in patients with neck pain. In this study, subjects were randomly assigned to 2 groups:

one group was assigned to manipulation with the Activator, the other to manual chiropractic manipulation using a standard technique. The Activator Methods Chiropractic Technique of leg length analysis was used to determine treatment locations in both the instrument group and the manual group. All treatments, both manual and instrumental, were applied by a single chiropractor. Subjects were treated until they were asymptomatic or received a maximum of 8 treatments, and were followed for 1 month after completion of therapy. The investigators reported that no significant differences were observed between the instrumental manipulation group and the manual manipulation group with respect to subjective outcomes (pain and disability) and objective outcomes (range of motion) ($p > 0.025$). The study has a number of important limitations, including the small sample size, so that the study may be under-powered to detect clinically significant differences in outcomes among groups. In addition, the small size of the study and the fact that all treatments were provided by a single chiropractor raise questions about the generalizability of the findings. The investigator who assessed the clinical outcomes was not blinded to group assignment, raising the possibility of examiner bias. The short duration of follow-up in this study does not allow one to compare the durability of results of these treatments. The statistical analysis used in this study was inappropriate to answer the key question about the effectiveness of the Activator compared to manual therapy in that the study used a superiority design rather than a more stringent non-inferiority design (i.e., the null hypothesis of this study was that there were no significant differences between the groups in clinical improvement). The investigators stated that future studies could benefit from including an untreated group and a sham treatment group to determine the true clinical benefits of these manipulative procedures. The investigators concluded that a randomized controlled clinical trial in a similar patient base with a larger sample size is necessary to verify the clinical relevance of these findings.

An unpublished study (Pfefer et al, 2007) compared the outcomes in terms of pain and function of acute low back pain patients treated with either Activator Methods Chiropractic Technique or a standard method of chiropractic manipulation (diversified chiropractic spinal manipulation). A total of 47 patients with acute or subacute low back pain were randomly assigned to the Activator Technique or manual chiropractic manipulation. Each treatment group had a single chiropractic practitioner. The Activator

doctor used the standard Activator leg length discrepancy protocols, whereas the manual therapy doctor used a combination of motion and static palpation to determine the areas to be treated. Subjects were treated with duration and frequency at the clinical discretion of each group's treating chiropractor, for up to 6 weeks. Subjects were assessed at study initiation, at weekly intervals for the first 3 weeks of therapy, and at week 6. The investigators reported that the null hypothesis of non-equivalence was rejected for measure of disability (the Modified Oswestry disability questionnaire score), but not for pain (Visual Analog Scores (VAS) for pain). This study avoided some of the limitations of the study by Woods et al, in that it used an equivalence design for statistical analysis rather than a superiority design; tolerance was set at 20 %, so that the 2 treatments could differ from each other by up to 20 % and still be considered equivalent. Outcomes were assessed in a blinded manner by student research assistants. The investigators noted that a clear weakness of this study is confounding of the provider with the technique, and that future studies could address this issue by assigning several providers of equal competence to deliver the technique. Other limitations of this study are the small sample sizes and limited duration of follow-up.

Kawchuk et al (2006) reported on a study comparing variability in the magnitude and duration of force produced by manual and instrument-based manipulation. In this study, 4 therapists (2 novices and 2 experts certified in the use of Activator instruments by the manufacturer) used 4 different mechanical instruments to apply force to a load cell fixed to a rigid surface. These 4 instruments included 2 spring-based instruments (the Activator IV and the Activator Signature), a compressed gas instrument (the Air Activator), and an electromechanical instrument (the Impulse from Neuromechanical Innovations, Phoenix, AZ). A different group of 2 experts licensed in chiropractic and 2 unlicensed novices used traditional manual techniques to apply force to a sensor mat. The investigators reported that manual applications of force were generally greater in magnitude and duration than those delivered by instrument. The mean force of all manual applications was 264 Newtons and the mean force duration was 145 milliseconds, whereas the mean force for all instrument applications was 171 Newtons and the average force duration was 0.963 milliseconds. The investigators reported that force-producing instrumentation exhibited less variation in absolute force and force duration compared to manual techniques. On average, the standard

deviation for all manual applications represented 16 % of the applied force and 23 % of the mean force duration. For all instrument applications, the standard deviation represented 4 % of the mean applied force and 5 % of the mean force duration. The investigators noted, however, that there were significant differences in absolute force between operators using the same instrument. The investigator concluded that the use of an instrument would be expected to reduce human inconsistency and result in reduced variation in magnitude and duration of force among operators. This study is limited in that it did not report on clinical outcomes of manual versus instrumented manipulation in humans.

A number of clinical studies have evaluated the effect of Activator treatment on autonomic functions (Yates et al, 1988; Peterson, 1997; Roy et al, 2008; Roy et al, 2009; Roy et al, 2013; Roffers et al, 2015); the clinical significance and implications of these findings, however, is uncertain. Yates et al (1988) examined the effectiveness of the Activator technique compared to sham Activator treatment in lowering blood pressure or no treatment in 21 patients with elevated blood pressure, finding that the Activator treatment significantly reduced blood pressure in the short-term. The investigators concluded that further research is necessary to evaluate the long-term effectiveness of treatment. "While spinal manipulative therapy appears to be effective in producing a temporary reduction in blood pressure immediately after treatment, the effect of such treatment in reducing blood pressure over a period of days or weeks is unknown and warrants further investigation."

Roffers et al (2015) conducted a randomized controlled trial to measure the effects of specific thoracic (T5 to T1) chiropractic adjustments on blood pressure and pulse rate on normotensive and hypertensive persons. After internal review board approval and informed consent, 290 subjects who met the inclusion criteria were randomly assigned to one of three groups: control (N = 95; no treatment, no placebo); placebo treatment (N = 96; sham adjustment with inactive device); or Activor treatment (N = 99). Subjects were seated in a relaxing climate-controlled room for a minimum of 15 min prior to obtaining a baseline blood pressure (BP) (systolic and diastolic) and pulse rate (PR) measurement with an electronic oscillometric BP monitor. The subjects were then moved to chairs stationed according to the study group in which they were assigned. Subjects had another BP and PR measured (anxiety BP

and PR measurements) after being called upon for active treatment, placebo treatment, or no treatment at all. Active treatment involved the use of the Activator IV adjusting instrument to correct subluxations detected according to the Activator Methods Chiropractic Technique for thoracic vertebrae T5 to T1. Placebo treatment was performed with an Activator II10 adjusting instrument in the off position which mimics all aspects of the treatment that is administered when in the on position but no manipulative force is delivered. Following active treatment (or placebo treatment or no treatment), subjects had their BP and PR measured once again. Subjects ranged in age from 18 to 100 years old (mean age = 52) and 66% of them were female. Systolic and diastolic BP decreased significantly (p = 0.0001) in the active treatment group, whereas no significant changes occurred in the placebo treatment and control groups. Similarly, PR decreased significantly (p = 0.0001) in the active treatment group, whereas no significant changes occurred in the placebo treatment and control groups.

Using a digitized infrared segmental thermometry (DIST) to measure cutaneous temperature (CT), Roy, et al. assessed the effect the Activator on cutaneous temperature during 2 different time recording periods (TRPs). Sixty-six healthy subjects (36 women and 30 men) without acute low back conditions or symptoms were recruited. Subjects were randomly divided into 2 groups based on the length of the acclimatization period (8 or 30 minutes; TRP(8) and TRP(30), respectively). In turn, each recording period group was divided into 3 subgroups (n = 11 per subgroup): treatment, sham, and control subgroups. Bilateral DIST was conducted at L-4 (TRP(30)) and L-5 (TRP(8)) using infrared cameras (Subluxation Station Insight 7000; Chiropractic Leadership Alliance, Mahwah, NJ). Before treatment (t(-0.5)), the TRP(8) CT was significantly different between the ipsilateral and the contralateral sides for all subgroups. At 10 minutes (t(10)) after intervention, CT increased significantly (P < .05) for the treatment group but not for the sham and control groups. In contrast, there were no significant differences in the TRP(30) CT before treatment between the ipsilateral and the contralateral sides; but at t(10), CT was significantly (P < 0.05) greater for all 3 subgroups compared with preintervention CT. The investigators concluded that contacting the skin with the instrument with (treatment group TRP(30)) or without (sham group TRP(30)) a thrust with a sustained pressure stronger than the loading principle taught in the Activator protocol or a thrust respecting the

standard loading principle (treatment group TRP(8)) of the instrument produced a CT cooling immediately after the adjustment. The investigators also observed that when contacting the skin with the instrument with a thrust respecting the standard loading principle (treatment group TRP(8)) of the instrument, it produced a secondary cooling at t(5) followed by a rewarming at t(10). Finally, contacting the skin with the instrument without a thrust and respecting the standard loading principle (sham TRP(8)) of the instrument did not produce a CT change.

Roy et al (2009) examined heart rate variability (HRV) in the presence or the absence of pain in the lower back, while receiving one chiropractic treatment at L5 from either a manually assisted mechanical force (Activator) or a traditional diversified technique spinal manipulation. A total of 51 participants were randomly assigned to a control (n = 11), 2 treatment, or 2 sham groups (n = 10 per group). Participants underwent an 8-minute acclimatizing period. The HRV tachygram (RR interval) data were recorded directly into a Suunto watch. We analyzed the 5-minute pretreatment and posttreatment intervals. The spectral analysis of the tachygram was performed with Kubios software. All groups decreased in value except the control group that reacted in the opposite direction, when comparing the pretests and posttests for the high-frequency component. The very low frequency increased in all groups except the control group. The low frequency decreased in all groups except the sham pain-free group. The low frequency-high frequency ratio decreased in the treatment pain group by 0.46 and in the sham pain-free group by 0.26. The low frequency-high frequency ratio increase was 0.13 for the sham pain group, 0.04 for the control group, and 0.34 for the treatment pain-free group. The mean RR increased by 11.89 milliseconds in the sham pain-free group, 18.65 milliseconds in the treatment pain group, and 13.14 milliseconds in the control group. The mean RR decreased in the treatment pain-free group by 1.75 milliseconds and by 0.01 milliseconds in the sham pain group. The investigators concluded that adjusting the lumbar vertebrae affected the lumbar parasympathetic nervous system output for this group of participants.

Roy et al (2013) reported on the effects of Activator treatment on paraspinal cutaneous temperature (PCT) for subjects with chronic low back pain and compare these PCT findings to subjects without chronic

low back pain. Two groups were created, a symptomatic treatment group (subjects with chronic low back pain, n = 11, 7 males, 4 females) and an asymptomatic, nontreatment group (asymptomatic subjects, n = 10, 6 males, 4 females). Outcomes included the modified Oswestry questionnaire and PCT measurements in the prone position after an 8-minute acclimation period. The treatment group received 9 Activator treatments over 2 weeks. Reevaluation was done 2 weeks after the initial evaluation for both groups. The preintervention Oswestry results (29.8% ± 11.8%) for the treatment group were higher than the asymptomatic group (10.2% ± 10.6%). The postintervention Oswestry results for the treatment group were 14.20 % ± 11.5%. The resulting Cohen's effect size of the spinal manipulation on the Oswestry evaluation is 0.58. The preintervention PCT showed higher temperature for the nontreatment group compared with the treatment group. Comparing the levels associated with low back pain, the nontreatment group PCT was stable, varying from 0.01°C to 0.02°C, whereas the treatment group PCT varied from 0.10°C to 0.18°C. The treatment group postintervention PCT showed an increase in temperature after the 9 visits; however, this did not reach the values of the asymptomatic group. The authors concluded that the percutanous temperature (PCT) readings for subjects with chronic low back pain were lower than the asymptomatic, nontreatment group. The PCT temperature of the treatment group increased after 9 treatments.

In a randomized controlled trial, Peterson et al (1997) assessed the effect of spinal manipulation with Activator upon visual analog scale (VAS) and pulse rates as proxies for the intensity of emotional arousal in phobic subjects exposed to a threat stimulus. The authors found significant decreases in VAS scores but no significant change in pulse rates after Activator treatment. Eighteen phobic community college student volunteers randomized into treatment and control groups. Visual analog scale (VAS) and pulse rates were obtained in response to the subjects' viewing their phobogenic stimulus. Spinal manipulation was performed while the subjects experienced emotional responses. Manual muscle testing was utilized to ascertain the associated spinal segments and involved emotion. Data were analyzed using analysis of variance for a repeated measures experimental design and Least Significant Differences (LSDs) for mean comparisons. Baseline, preintervention and postintervention pulse rates were not statistically different for the control and treatment groups (p = .0807). VAS postintervention mean for the

spinal manipulation group was significantly lower than the control means ($p = .05$) and from its corresponding preintervention mean ($p = .001$). The authors stated that the mechanism for this effect of Activator on VAS is not known.

Other clinical studies of Activator have focused on intermediate endpoints of inflammatory markers (Roy et al, 2010), EMG activity (Keller and Colloca, 2010; Yu et al, 2010), and pressure pain thresholds (Yu et al, 2010); the relationship of these intermediates to patient outcomes is uncertain. Roy et al (2010) reported on the responses of inflammatory markers interleukin-6 (IL-6) and C-reactive protein (CRP) after a series of 9 Activator treatments. Twenty-one participants were assigned to a treatment or a control group. Only the treatment group received 9 Activator treatments. Pre- and post-intervention measures were recorded for blood samples for detection of proinflammatory cytokines IL-6 and CRP. The investigators reported that mediators of inflammation (IL-6 and high-sensitivity CRP) were modified by the intervention received in the treatment group, and the effect size demonstrated a tendency toward the control group values. The authors reported that the 9 Activator treatments caused the mediators of inflammation to present a normalization response in individuals suffering from chronic low back pain. The main limitation of this study is that it reports on intermediate endpoints; the relationship of these endpoints to patient outcomes is unknown.

In a prospective clinical trial, Keller and Colloca (2010) assessed whether Activator treatment affects paraspinal muscle strength as assessed through use of surface electromyography (sEMG). Forty subjects with low back pain (LBP) participated in the study. Twenty patients with LBP (9 females and 11 males with a mean age of 35 years and 51 years, respectively) and 20 age- and sex-matched sham-spinal manipulative therapy (SMT)/control LBP subjects (10 females and 10 males with a mean age of 40 years and 52 years, respectively) were assessed. Twenty consecutive patients with LBP (SMT treatment group) performed maximum voluntary contraction (MVC) isometric trunk extensions while lying prone on a treatment table. Surface, linear-enveloped sEMG was recorded from the erector spinae musculature at L3 and L5 during a trunk extension procedure. Patients were then assessed through use of the Activator Methods Chiropractic Technique protocol, during which time they were treated through use of Activator treatment. The Activator

treatment was followed by a dynamic stiffness and algometry assessment, after which a second or post-MVC isometric trunk extension and sEMG assessment were performed. Another 20 consecutive subjects with LBP were assigned to one of two other groups, a sham-Activator treatment group and a control group. The sham-Activator treatment group underwent the same experimental protocol with the exception that the subjects received a sham-Activator treatment and dynamic stiffness assessment. The control group subjects received no spinal manipulation treatment, stiffness assessment, or algometry assessment intervention. Within-group analysis of MVC sEMG output (pre-Activator treatment vs post-Activator treatment sEMG output) and across-group analysis of MVC sEMG output ratio (post-Activator sEMG/pre-Activator sEMG output) during MVC was performed through use of a paired observations t test (POTT) and a robust analysis of variance (RANOVA), respectively. Surface, linear-enveloped EMG recordings during isometric MVC trunk extension were used as the primary outcome measure. Nineteen of the 20 patients in the Activator treatment group showed a positive increase in sEMG output during MVC (range, -9.7% to 66.8%) after the active Activator treatment and stiffness assessment. The Activator treatment group showed a significant (POTT, $P < 0.001$) increase in erector spinae muscle sEMG output (21% increase in comparison with pre-Activator treatment levels) during MVC isometric trunk extension trials. There were no significant changes in pre-treatment or vs post-treatment MVC sEMG output for the sham-Activator (5.8% increase) and control (3.9% increase) groups. Moreover, the sEMG output ratio of the Activator treatment group was significantly greater (robust analysis of variance, $P = 0.05$) than either that of the sham-Activator treatment group or that of the control group. The investigators concluded that the results of this preliminary clinical trial demonstrated that Activator treatment results in a significant increase in sEMG erector spinae isometric MVC muscle output. These findings indicate that altered muscle function may be a potential short-term therapeutic effect of Activator treatment, and they form a basis for a randomized, controlled clinical trial to further investigate acute and long-term changes in low back function.

Yu et al (2010) investigated the effects of Activator treatment targeted to the low-back region on changes in pressure pain thresholds (PPTs) and basal electromyographic activity (BEA) in asymptomatic participants. A

repeated-measures, single-blind, randomized trial was conducted on 30 participants, 19 men and 11 women (mean age, 24.5±3.9 years), without a current history of low-back pain. Each participant attended all 2 treatment group sessions and received Activator treatment or a sham manipulation procedure. Bilateral PPT levels over L5-S1 zygapophyseal joints, L5 dermatome, and first dorsal interossei in the hand and bilateral BEA of low back and neck region were assessed pre- and posttreatment by an assessor blinded to the treatment allocation of the participant. A 3-way analysis of variance with time (pre-post) and side (ipslateral, contralateral to the intervention) as within-group variable and intervention (manipulation or sham) as between-group variable was used to evaluate changes in PPT. A paired sample t test was used to analyze the differences between pre- and posttreatment in BEA. The group vs time interaction was statistically significant for PPT irrespective of the site tested or the side treated. Participants receiving the Activator treatment experienced greater improvement in PPT when compared with the control group. Paired sample t tests for BEA only show an immediate decrease in BEA of the paraspinal muscle on the pelvic deficiency side of the low-back region.

In a case series study (n = 9), Devocht et al (2003) reported that the symptoms of temporomandibular disease improved following a course of treatment using the Activator methods. The authors concluded that further investigation of this type of chiropractic treatment for patients with the articular type of temporomandibular disease is warranted. Moreover, Fuhr and Menke (2005) stated that the Activator Adjusting Instrument may be a clinically useful tool, but its ultimate scientific validation requires testing using sophisticated research models in the areas of neurophysiology, biomechanics, and statistical analysis. This is in agreement with the observation of Polkinghorn (1998) who noted that instrument-delivered adjustments (i.e., the Activator Adjusting Instrument) may provide benefit in cases of cervical disc protrusion in which manual manipulation causes an exacerbation of the symptoms or is contraindicated altogether. The author concluded that further study in this area should be made via large scale studies organized in an academic research setting.

Devocht et al (2013) reported on a pilot study of the feasibility of conducting a larger trial to evaluate chiropractic treatment of temporomandibular disorders (TMDs). The authors stated that this pilot study was a necessary step to prepare for a larger study that will provide clinicians with information that should be helpful when discussing treatment options for patients with TMD. The authors assigned 80 participants randomly into one of the following four groups, all of which included a comprehensive self-care program: reversible interocclusal splint therapy (RIST), Activator treatment, sham Activator treatment and self-care only. They made assessments at baseline and at month 2 and month 6, including use of the Research Diagnostic Criteria for Temporomandibular Disorders. The authors screened 721 potential participants and enrolled 80 people; 52 participants completed the six-month assessment. The adjusted mean change in current pain over six months, as assessed on the 11-point numerical rating scale, was 2.0 (95 percent confidence interval, 1.1-3.0) for RIST, 1.7 (0.9-2.5) for self-care only, 1.5 (0.7-2.4) for Activator treatment and 1.6 (0.7-2.5) for sham Activator treatment. The authors also assessed bothersomeness and functionality. The authors found the study design and methodology to be manageable. They stated that they had gained substantial knowledge to aid in conducting a larger study. The authors stated that Activator treatment, RIST and self-care should be evaluated in a future comparative effectiveness study.

In a prospective, randomized, comparative clinical trial, Shearar et al (2005) examined the effect of instrument-delivered compared with traditional manual-delivered thrust chiropractic adjustments in the treatment of sacroiliac joint syndrome. A total of 60 patients with sacroiliac syndrome were randomized into 2 groups of 30 subjects. Each subject received 4 chiropractic adjustments over a 2-week period and was evaluated at 1-week follow-up. One group received side-posture, high-velocity, low-amplitude chiropractic adjustments; the other group received mechanical-force, manually-assisted chiropractic adjustments using an Activator Adjusting Instrument (Activator Methods International, Ltd, Phoenix, AZ). No significant differences between groups were noted at the initial consultation for any of the outcome variables. Statistically significant improvements were observed in both groups from the 1st to 3rd, 3rd to 5th, and 1st to 5th consultations for improvements ($p < 0.001$) in mean numerical pain rating scale 101 (group 1, 49.1 to 23.4; group 2,

48.9 to 22.5), revised Oswestry Low Back Pain Disability Questionnaire (group 1, 37.4 to 18.5; group 2, 36.6 to 15.1), orthopedic rating score (group 1, 7.6 to 0.6; group 2, 7.5 to 0.8), and algometry measures (group 1, 4.8 to 6.5; group 2, 5.0 to 6.8) for first to last visit for both groups. The authors concluded that the findings of this study indicated that a short regimen of either mechanical-force, manually-assisted or high-velocity, low-amplitude chiropractic adjustments were associated with a beneficial effect of a reduction in pain and disability in patients diagnosed with sacroiliac joint syndrome. Neither mechanical-force, manually-assisted nor high-velocity, low-amplitude adjustments were found to be more effective than the other in the treatment of this patient population.

Gemmell and Miller (2010) reported on a trial comparing manipulation, segmental mobilization and Activator treatment of mechanical neck pain that was stopped because of poor recruitment. A pragmatic randomised clinical trial was undertaken. Patients who met eligibility criteria were randomised into three groups. One group was treated using specific segmental high velocity low amplitude manipulation (diversified), another by specific segmental mobilisation, and a third group by the Activator instrument. All three groups were also treated for any myofascial distortions and given appropriate exercises and advice. Participants were treated six times over a three-week period or until they reported being pain free. The primary outcome measure for the study was Patient Global Impression of Change (PGIC); secondary outcome measures included the Short-Form Health Survey (SF-36v2), the neck Bournemouth Questionnaire, and the numerical rating scale for pain intensity. Participants also kept a diary of any pain medication taken and noted any perceived adverse effects of treatment. Outcomes were measured at four points: end of treatment, and 3, 6, and 12 months thereafter. Between January 2007 and March 2008, 123 patients were assessed for eligibility, of these 47 were considered eligible, of which 16 were allocated to manipulation, 16 to the Activator instrument and 15 to the mobilisation group. Comparison between the groups on the PGIC adjusted for baseline covariants did not show a significant difference for any of the endpoints. Within group analyses for change from baseline to the 12-month follow up for secondary outcomes were significant for all groups on the Bournemouth Questionnaire and for pain, while the mobilisation group had a significant improvement on the PCS and MCS subscales of the SF-36v2. Finally, there were no moderate, severe, or long-lasting adverse

effects reported by any participant in any group. The authors stated that, although there were no significant dfferences between groups, the small size of the study may have left it underpowered to detect clinically significant differences in safety and efficacy between groups. The authors concluded that this pragmatic trial should be repeated with a larger sample size.

Schneider et al (2010) reported on an observational prospective cohort study to explore the treatment effect of Activator versus manual manipulation for acute low back pain. Ninety-two patients with a history of acute low back pain were recruited from 3 private chiropractic offices, 2 of which used manual lumbar manipulation and 1 used Activator as their primary modes of treatment. The chiropractors used their "treatment-as-usual" protocols for a maximum of 8 visits or 4 weeks, whichever occurred first. Primary outcome measures were changes in Numeric Pain Rating Scale (NPRS) and Oswestry Disability Index (ODI) scores from baseline to 4 weeks. The linear regression models were adjusted for baseline NPRS and ODI scores, age, and treatment expectancy. Comparison of baseline characteristics did not show any significant differences between the groups except for age (38.4 vs 49.7 years, $P < .001$) and treatment expectancy (5.7 vs 6.3, $P = .003$). Linear regression revealed significantly lower NPRS scores in the manual manipulation group at 4 weeks (beta = -1.2; 95% confidence interval, -2.1 to -.28) but no significant difference in ODI scores between the 2 groups at 4 weeks (beta = 1.5; 95% confidence interval, -8.3 to 2.4). Treatment expectancy was found to have a significant main effect on both NPRS and ODI scores at 4 weeks. Exploratory analysis of the clinical patterns of care between the clinicians revealed significant differences in treatment frequency, duration, modality, and radiograph use between the 2 cohorts. These differences may have confounded the comparison of outcomes between groups treated with Activator versus manual manipulation. The authors concluded that this study highlights the challenges inherent with conducting research that allows for "treatment as usual." The authors stated that the data and experience derived from this investigational study will be used to design a future randomized clinical trial in which tighter controls will be imposed on the treatment protocol.

Schneider et al (2015) reported on a randomized controlled trial comparing manual-thrust manipulation (MTM) versus mechanical-assisted manipulation (MAM) with Activator; and manipulation versus usual medical care (UMC). The authors stated that MTM is a common treatment for low back pain (LBP), and that claims that MAM is an effective alternative to MTM have yet to be substantiated. A total of 107 adults with onset of LBP within the past 12 weeks were randomized to 1 of 3 treatment groups: MTM, MAM, or UMC. Outcome measures included the Oswestry LBP Disability Index (0-100 scale) and numeric pain rating (0-10 scale). Participants in the manipulation groups were treated twice weekly during 4 weeks; subjects in UMC were seen for 3 visits during this time. Outcome measures were captured at baseline, 4 weeks, 3 months, and 6 months. Linear regression showed a statistically significant advantage of MTM at 4 weeks compared with MAM (disability = -8.1, P = 0.009; pain = -1.4, P = 0.002) and UMC (disability = -6.5, P = 0.032; pain = -1.7, P < 0.001). Responder analysis, defined as 30% and 50% reductions in Oswestry LBP Disability Index scores revealed a significantly greater proportion of responders at 4 weeks in MTM (76%; 50%) compared with MAM (50%; 16%) and UMC (48%; 39%). Similar between-group results were found for pain: MTM (94%; 76%); MAM (69%; 47%); and UMC (56%; 41%). No statistically significant group differences were found between MAM and UMC, and for any comparison at 3 or 6 months. The investigators concluded that MTM provides greater short-term reductions in self-reported disability and pain scores compared with UMC or MAM with Activator. The authors stated that "these results contradict prior assumptions of therapeutic equivalence between manual thrust and mechanical-assisted types of manipulation."

Commenting on this study by Schneider et al, Guevarra and Seffinger (2015) noted that one major limitation is that other outcome measures were not examined, particularly nonprescription medication use. They commented that, because all participants were allowed to use analgesics and nonsteroidal anti-inflammatory medications, it would be interesting to see if any differences between treatment groups existed or if any changes occurred in use over time. Another limitation of this study by Schneider, et al. noted by Guevarra and Seffinger is the lack of a sham therapy or control group. "However, the findings in this study are promising in that MTM [manual thrust manipulation] can be considered part an effective treatment plan for patients with LBP."

Fuhr et al (2005) reviewed the literature on the Activator Adjusting Instrument (AAI) and Activator Methods Chiropractic Technique of clinical assessment. Online resources were searched including Index to Chiropractic Literature, EBSCO Online, MANTIS, CHIROLARS, CINAHL, eJournals, Ovid, MDConsult, Lane Catalog, SU Catalog, and Pubmed. Relevant peer-reviewed studies, commentaries, and reviews were selected. Studies fell into 2 major content areas: instrument adjusting and the analysis system for therapy application. Studies were categorized by research content type: biomechanical, neurophysiological, and clinical. Each study was reviewed in terms of contribution to knowledge and critiqued with regard to quality. The authors found more than 100 studies related to the AAI and the technique, including studies on the instrument's mechanical effects, and a few studies on clinical efficacy. With regard to the analysis, there is evidence for good reliability on prone leg-length assessment, but to date, there is only 1 study evaluating the Activator Methods Chiropractic Technique analysis. The authors found that a body of basic science and clinical research has been generated on the AAI since its first peer-reviewed publication in 1986. The authors stated that the Activator analysis may be a clinically useful tool, but its ultimate scientific validation requires testing using sophisticated research models in the areas of neurophysiology, biomechanics, and statistical analysis.

Huggins et al (2012) reported on a systematic evidence review of Activator treatment in the treatment of musculoskeletal disorders, finding no significant difference with manual techniques. The authors, however, found only 8 clinical trials that sought to determine the clinical effectiveness of the Activator treatment. The authors noted that none of the clinical trials included in the systematic evidence review were randomized clinical trials; and all the studies used small study populations, ranging from 8 to 92 subjects. Moreover, not all studies were adequately controlled with respect to both subject and examiner blinding, with 5 of the studies being assigned a 0 out of 5. An additional limitation was that all but one study failed to either strategize or adjust for relevant baseline characteristics. Due to the lack of long-term follow-up care and the use of a single treatment intervention, contamination and co-intervention grading had to be assumed in 4 of the 8 studies which may have further influenced the overall quality of these studies. A further

limitation was that 7 of the 8 studies utilized a previously established patient base as study subjects, thus introducing the possible confounding factors of treatment expectancy and type II errors.

The Atlas orthogonal technique is an upper-cervical, spinal-corrective procedure that is intended to restore a person’s balance and stimulate the natural-healing capabilities normally present in the body. Unlike other chiropractic procedures, there is no twisting or cracking involved. Besides correcting spinal issues, the Atlas orthogonal technique is thought to help with various conditions such as arthritis, migraine headaches, asthma, and fibromyalgia. However, there is a lack of evidence regarding the clinical value of this technique.

The Blair technique is a specific system of analyzing and adjusting the upper cervical vertebrae. Attention is given to the atlas and axis (the first 2 cervical vertebrae) since they are the most freely moveable vertebrae in the spinal cord and the ones most commonly mis-aligned. The objective of the Blair technique is not to diagnose or treat diseases or conditions, but to analyze and correct vertebral subluxations such that the body can repair and maintain health from within. However, there is a lack of evidence regarding the clinical value of this technique.

Biogeometric integration has been described as a conceptual understanding that enhances chiropractors' knowledge of the human body. Seminars on biogeometric integration provide an understanding of the innate geometry of the body and force dynamics surrounding the creation and release of subluxations. The philosophy, science, and art of chiropractic are examined from a post-Newtonian point of view, providing the opportunity to express and understand chiropractic in accord with contemporary science. Through understanding of the innate geometry of the body, chiropractors are thought to be able to more effectively and gently release the subluxation and assess the effectiveness of the adjustment. The geometric understanding of the body also serves to bridge the gap between the many techniques of chiropractic by providing a common language and understanding from which to converse. However, there is a lack of evidence regarding the clinical value of this approach.

The Whitcomb Technique, advocated by Paul Whitcomb, allegedly can cure patients with fibromyalgia. It entails a quick neck manipulation, 3 times a day, 5 days a week, for at least 2 months. The number of neck manipulations ranged from 60 to 143. However, there is a lack of evidence regarding the clinical value of this method.

There is inadequate evidence of the effectiveness of Neuro Emotional Technique (NET) for attention deficit hyperactivity disorder (ADHD) or other indications. Karpouzis et al (2009) stated that an abundance of literature is dedicated to research for the treatment of ADHD. Most, is in the area of pharmacological therapies with less emphasis in psychotherapy and psychosocial interventions and even less in the area of complementary and alternative medicine (CAM). The use of CAM has increased over the years, especially for developmental and behavioral disorders, such as ADHD. Almost 2/3 of parents with children with ADHD have used CAM. Medical evidence supports a multi-disciplinary approach (i.e., pharmacological and psychosocial) for the best clinical outcomes. The NET, a branch of chiropractic, was designed to address the biopsychosocial aspects of acute and chronic conditions including non-musculoskeletal conditions. Anecdotally, it has been suggested that ADHD may be managed effectively by NET. A randomized, placebo-controlled, double-blind, clinical trial was designed to assess the effectiveness of NET on a cohort of children with medically diagnosed ADHD. Children aged 5 to 12 years who met the inclusion criteria were randomized to one of three groups. The control group continued on their existing medical regimen and the intervention and placebo groups had the addition of the NET and sham NET protocols added to their regimen, respectively. These 2 groups attended a clinical facility twice-weekly for the first month and then once-monthly for 6 months. The Conners' Parent and Teacher Rating Scales (CRS) were used at the start of the study to establish baseline data and then in 1-month and in 7-month time, at the conclusion of the study. The primary outcome measures chosen were the Conners' ADHD Index and Conners' Global Index. The secondary outcome measures chosen were the DSM-IV: Inattentive, the DSM-IV: Hyperactive-Impulsive, and the DSM-IV: Total subscales from the Conners' Rating Scales, monitoring changes in inattention, hyperactivity and impulsivity. Calculations for the sample size were set with a significance level of 0.05 and the power of 80 %, yielding a sample size of

93. The authors noted that the present study should provide information as to whether the addition of NET to an existing medical regimen can improve outcomes for children with ADHD.

Bablis et al (2009) described the profile of patients presenting to a private chiropractic clinic specializing in NET; and identified trends in the presentation of symptoms from these patients. A total of 761 consecutive new patients presented to a large, multi-doctor chiropractic clinic in which practitioners all adopt a similar philosophical paradigm and practice NET From January 2005 to December 2005, self-referred patients completed a new patient questionnaire, in which they self-reported 1 primary complaint for why they were visiting the practitioner. Pre-determined patient information was entered manually into a database and basic descriptive statistics extracted. Overall, 67.3 % of participants were female and 32.6 % of the participants were between the ages of 31 and 40; 54.8 % of patients presented with a primary musculoskeletal complaint and 36.0 % a non-musculoskeletal complaint. Of the musculoskeletal complaints, 40.8 % of patients presented with back pain, 20.9 % with neck pain and 11.5 % with shoulder pain. The most common form of non-musculoskeletal complaint was immune and recurrent infections (13.9 %), stress and anxiety (12.8 %) and depression (10.9 %). 41.4 % of participants reported a first time complaint, however, of the patients who had had the presenting complaint before 60.7 % reported as having the complaint for greater than 1 year. Musculoskeletal and non-musculoskeletal participants had similar pain profiles. The authors concluded that this retrospective analysis is the first comprehensive description of the scope of NET patients and their presenting complaints. The patient profile of this NET clinic has a higher degree of non-musculoskeletal patients than that usually reported in non-NET chiropractic offices, and other forms of chiropractic previously described in the literature. They stated that further cross-sectional research is required to determine if this particular clinic is indicative of all NET practices and whether the presenting symptoms, especially the non-musculoskeletal, are resolved with NET.

There is insufficient evidence to support the use of chiropractic in treatment of non-neuromusculoskeletal conditions in children. In a review *Chiropractic Diagnosis and Management of Non-musculoskeletal Conditions in Children and Adolescents*, Ferrance and Miller (2010) noted

that a great deal has been published in the chiropractic literature regarding the response, or lack thereof, of various common pediatric conditions to chiropractic care. The majority of that literature is of low scientific value (i.e., case reports or case series). The purpose of this review was to summarize the literature from the point of view of clinicians, rather than researchers, and to discuss some additional detail of the conditions themselves. Databases searched were PubMed, Mantis, Index to Chiropractic Literature, and CINAHL. Keywords were chiropractic paired with colic, crying infant, nocturnal enuresis, asthma, otitis media and ADHD. Most of the published literature centers around case reports or series. The more scientifically rigorous studies show conflicting results for colic and the crying infant, and there is little data to suggest improvement of otitis media, asthma, nocturnal enuresis or attention deficit hyperactivity disorder. The authors concluded that the efficacy of chiropractic care in the treatment of non-musculoskeletal disorders has yet to be definitely proven or disproven, with the burden of proof still resting upon the chiropractic profession.

There is a paucity of evidence of the effectiveness of spinal manipulation for treatment of headaches. Vernon et al (2009) stated that tension-type headache (TTH) is the most common headache experienced by adults in Western society. Only 2 clinical trials of spinal manipulation for adult TTH have been reported, neither of which was fully controlled. In 1 trial, spinal manipulation was compared to amitriptyline. This trial was stopped prematurely due to poor recruitment. The purposes of this study were to

(i) describe the trial protocol, as it contained several novel features, (ii) report the limited data set obtained from sample of completed subjects, and (iii) discuss the problems that were encountered in conducting this study. Sufferers of TTH with more than 10 headaches per month were randomly assigned to 4 groups: (i) real cervical manipulation + real amitriptyline, (ii) real cervical manipulation + placebo amitriptyline, (iii) sham cervical manipulation + real amitriptyline, and (iv) sham cervical manipulation + placebo amitriptyline. A baseline period of 4 weeks was followed by a treatment period of 14 weeks. The primary outcome was headache frequency obtained from a headache diary in the last 28 days of the treatment period. A total of 19 subjects completed the trial. In the unadjusted

analysis, a statistically significant main effect of chiropractic treatment was obtained (-2.2 [-10.2 to 5.8], p = 0.03), which was just below the 3-day reduction set for clinical importance. As well, a clinically important [corrected] effect of the combined therapies was obtained (-9 [-20.8 [corrected] to 2.9], p = 0.13), but this did not achieve statistical significance. In the adjusted analysis, neither the main effects of chiropractic nor amitriptyline were statistically significant or clinically important; however, the effect of the combined treatments was -8.4 (-15.8 to -1.1), which was statistically significant (p = 0.03) and reached the criterion for clinical importance. The authors concluded that although the sample size was smaller than initially required, a statistically significant and clinically important effect was obtained for the combined treatment group. There are considerable difficulties with recruitment of subjects in such a trial. They stated that this trial should be replicated with a larger sample.

Haas et al (2010) presented a preliminary model to identify the effects of expectancy of treatment success and the patient-provider encounter (PPE) on outcomes in an open-label randomized trial of spinal manipulation for cervicogenic headache. A total of 80 subjects with chronic cervicogenic headache (CGH) were randomized to 4 groups: 2 levels of treatment dose (8 or 16) and 2 levels of therapy from a chiropractor (spinal manipulation or light massage). Providers were instructed to have equal enthusiasm for all care. Structural equation modeling with standardized path coefficients (beta) was used in a path analysis to identify the effects of patient expectancy and the PPE on CGH pain. The model included monthly pain from baseline to 12 weeks. Expectancy and PPE were evaluated on Likert scales. The patient-provider encounter was measured as patient perception of chiropractor enthusiasm, confidence, and comfort with care. Baseline patient expectancy was balanced across groups. The PPE measures were balanced across groups and consistent over the 8-week treatment period. Treatment and baseline pain had the strongest effects on pain outcomes (|beta| = 0.46 to 0.59). Expectations had little effect on pain (abs value(beta) < 0.15). The patient-provider encounter had a weak effect on pain (abs value(beta) = 0.03 to 0.27) and on subsequent confidence in treatment success (abs value(beta) = 0.09 and 0.12). The authors concluded that encouraging equipoise in the PPE and balancing expectancy across treatment groups may protect against some

confounding related to the absence of blinding in a randomized controlled trial of pain. In this trial, their effects were found to be small relative to the effects of treatment and baseline values.

In a multi-center, prospective, randomized, placebo-controlled, and blinded study, Borusiak and colleagues (2010) examined the effectiveness of cervical spine manipulation in children and adolescents with suspected cervicogenic headaches. A total of 52 children and adolescents (21 boys and 31 girls) aged 7 to 15 years were assigned either to placebo or true manipulation with another 2-month follow-up. Main outcome measures were percentage of days with headache, total duration of headache, days with school absence due to headache, consume of analgesics, intensity of headache. These investigators did not find a significant difference between the placebo group and the true manipulation group with respect to the defined main outcome measures. The authors concluded that they were unable to show an efficacy of cervical spine manipulation in 52 children and adolescents with suspected cervicogenic headaches.

There is little reliable evidence to support the use of chiropractic in treatment of idiopathic dizziness. In a pilot study, Hawk et al (2009) collected preliminary information on the effect of a limited and extended course of chiropractic care on balance, chronic pain, and associated dizziness in a sample of older adults with impaired balance. These investigators conducted a randomized trial targeting a sample size of 30, comparing 2 schedules of chiropractic care to a no-treatment group. Group 1 (limited schedule) was treated for 8 weeks, group 2 (extended schedule) was treated for 8 weeks and then once-monthly for 10 months, and group 3 received no treatment. Assessments were made at baseline and 1, 2, 6, and 12 months later. The primary outcome was changed in the Berg Balance Scale (BBS) from baseline to 1 year. Changes in the Pain Disability Index (PDI) and Dizziness Handicap Index (DHI) were also measured. A total of 34 patients were enrolled, 13 in group 1, 15 in group 2, and 6 in group 3. Only 5 had baseline BBS scores less than 45, indicating increased risk for falls. There were no treatment-related adverse events. Nine patients dropped out by 1 year. No significant differences within or between groups in median BBS from baseline to 12 months were observed. Median PDI scores improved more from baseline to 1 year in group 2 compared with groups 1 and 3 ($p = 0.06$, Kruskal-

Wallis test). For the 9 patients with dizziness, a clinically significant improvement in DHI scores of groups 1 and 2 was observed at 1 month and remained lower than baseline thereafter; this was not true of group 3. The authors concluded that further investigation of the possible benefit of chiropractic maintenance care (extended schedule) for balance and pain-related disability is feasible and warranted, as well as both limited and extended schedules for patients with idiopathic dizziness.

In a pilot study, Lewis et al (2006) examined if the active therapeutic movement (ATM2) can decrease low back pain (LBP), increase range of motion (ROM) and what the mechanism may be that is responsible for any decrease in pain. The ATM2 was shown to be effective in reducing LBP complaints although not significantly better than the abdominal hollowing exercise. Subjects were all students in their 20's and the overall presenting pain levels were low to start. The fact that the ATM2 did not significantly decrease LBP more than the mat exercise is not surprising as abdominal hollowing exercises are often prescribed for patients with LBP. The ATM2 was shown to be effective in increasing lumbar ROM whereas the mat exercise was not. The ATM2 did not appear to impact central nervous system re-programming of the transverse abdominus (TrA) muscle based on this procedure. However, studies that have looked at TrA timing have utilized needle electromyography (EMG) and this study used surface EMG that only can pick up the reflection of TrA activity. In addition, the software program used was difficult to read the extremely short time values necessary to accurately measure timing of the trunk muscles. Based on the results of this pilot study, the ATM2 has potential for helping patients with LBP and warrants further study.

The Koren Specific Technique (KST) appears to be a new system of analysis in chiropractic. With the KST method, the adjustment is generally made with an instrument called the "Arthrostim" although finger pressure can also be used. The KST allegedly opens up a new horizon on the analysis and correction of health problems by accessing the binary information of the holographic body, which supposedly enables a trained practitioner to access information about a patient's physiology that otherwise would not be available. However, there is a lack of evidence regarding the effectiveness of this approach.

Ernst (2009) noted that some chiropractors claim that spinal manipulation is an effective treatment for infant colic. The author performed a systematic review aimed at evaluating the evidence for this claim. Four databases were searched and 3 randomized controlled trials met all the inclusion criteria. The totality of this evidence fails to show the effectiveness of this treatment. The author concluded that the above claim is not based on convincing data from rigorous clinical trials.

According to the International Chiropractic Pediatric Association (Ohm, 2006), the Webster protocol is a specific chiropractic sacral analysis and diversified adjustment. The goal of the adjustment is to reduce the effects of sacral subluxation/SI joint dysfunction. In so doing neuro-biomechanical function in the pelvis is facilitated. Cohain (2007) stated that techniques for turning a term breech baby include

(i) external cephalic version (ECV) using hands and ultrasound only; (ii) acupuncture point stimulation, by needle or moxibustion; (iii) chiropractic "Webster" technique; (iv) hypnotherapy; and (v) special exercises. The author noted that 50 % of breech fetuses at 34 weeks will turn by themselves to head down by 38 weeks. Therefore, to be considered effective, a technique for turning breech must turn the baby and keep it turned more than 50 % of the time. Only ECV with an experienced practitioner has been documented to have a greater than 50 % success rate at 37 weeks; in 95 % of cases the head stays down. Furthermore, an UpToDate review on "Overview of breech presentation" (Hofmeyr, 2011) does not mention the use of chiropractic or the Webster Technique.

Ernst (2011) stated that many chiropractors believe that chiropractic treatments are effective for gastro-intestinal (GI) disorders. In a systematic review, the author evaluated the evidence from controlled clinical trials supporting or not supporting this notion. A total of 6 electronic databases were searched for relevant studies. No limits were applied to language or publication date. Prospective, controlled, clinical trials of any type of chiropractic treatment for any type of GI problem, except infant colic, were included. Only 2 trials were found – 1 was a pilot study, and the other had reached a positive conclusion; however,

both had serious methodological flaws. The author concluded that there is no supportive evidence that chiropractic is an effective treatment for GI disorders.

The FAKTR (Functional and Kinetic Treatment with Rehab) Approah was developed about 9 years ago by Greg Doerr, D.C. and Tom Hyde, D.C. who began to experiment with treating soft tissue/fascial disorders through the use of instruments. Both physicians were trained in a variety of soft tissue techniques including instrument-assisted soft tissue mobilization (IASTM) and decided to incorporate their previous training into a concept that included function and treatment of the kinetic chain while utilizing various forms of rehabilitation at the same time. They also incorporated treatment in the position of provocation (pain, loss of range of motion, feeling of tightness within the fascia/soft tissues) and during motion. The FAKTR approach incorporates all of the above variations to evaluate and treat soft tissue/fascial conditions. However, there is a lack of evidence regarding the effectiveness of the FAKTR Approach.

According to the Family Chiropractic Wellness Center, the Gonzalez Rehabilitation Technique (GRT) is a collection of patented techniques that evaluate and restore major nerves in the body. This approach supposedly makes the body function more efficiently by allowing previously wasted energy to be used for healing. The GRT does not treat any conditions. More importantly, the GRT focuses on "up-regulating" the nerves that may be associated to a condition so that the body heals itself; GRT is a technique that improves the way the nerves activate. An analogy is that if one can visualize a muscle or organ being controlled by a dimmer switch, one may be able to understand how 10 individuals with the exact same injury/condition can each have a unique level of dysfunction. In many cases the muscle or organ may be only slightly dimmed with minimal symptoms of pain, decreased range of motion, decreased strength and impaired organ function. And in other instances it may be completely dimmed, resulting in debilitating pain, paralysis, and poor organ function. In any case, the GRT is similar regardless of the level of dysfunction. The GRT can be directed to specific nerve groups to help patients with certain conditions. For example: the foot is controlled at the S1, L5 and L4 spinal levels. If anyone has ANY condition affecting the foot (e.g., broken foot, diabetic ulcer on the foot, hammer toes, heel spurs, plantar fasciitis, and sprained ankle, etc.), one or more of these

nerves are affected and by "up-regulating" these nerves the function will return and the conditions/symptoms improve if not completely disappear. The GRT practitioners are trained in various methods of correction including manual, instrument and light therapy techniques; and they report success of this approach in treating patients with various conditions including but not limited to:

- Autoimmune diseases: Guillain-Barre syndrome, multiple sclerosis, rheumatoid arthritis
- Brain injury: Bell's palsy, paralysis, speech and swallowing dysfunction, stroke
- Joint and bone injury: Broken bones, decreased joint space, ligament tears, post-surgery
- Spinal cord injury: Paralysis, sensory and motor injury
- Sports injury: Decreased range of motion, muscle and joint pain.

There is a lack of evidence regarding the effectiveness of GRT in the treatment of pain, musculoskeletal disorders and other conditions.

Dynamic spinal visualization is a general term used to describe several different imaging technologies, including digital motion x-ray and videofluoroscopy, also known as cineradiography.

Digital motion x-ray (DMX) is a video-based fluoroscopy system, involving the use of either film x-ray or computer-based x-ray 'snapshots' taken in sequence. The procedure is performed with the patient standing and actively moving in a weight bearing position within the system. Film x-rays are digitized into a computer for manipulation while computer-based x-rays are automatically created in a digital format. The digitized images are then put in order using a computer program and played on a video monitor, creating a moving image of the body. DMX allows clinicians to view the spine and extremity articulations in real-time at 30 exposures per second, and evaluate several aspects of the body's structures such as intervertebral flexion and extension to determine the presence or absence of abnormalities.

Videofluoroscopy and cineradiography are different names for the same procedure that utilizes a technique called fluoroscopy to create real-time video images of internal structures of the body. Unlike standard x-rays

that take a single picture at one point in time, fluoroscopy works more like a video camera, providing motion pictures of the inside the of body. The findings can be displayed in real time on a video monitor or recorded to allow computer analysis or evaluation at a later time.

The Therapeutic (Wobble) Chair (Pettibon System, Inc., Chehalis, WA) is a patented, height adjustable stool with a specially-designed seat. The seat provides 360 degrees of rotation, 40 degrees of side-to-side flexion and 35 degrees of front-to-back flexion on a universal type joint to facilitate all possible combinations of exercise motion needed for lumbar disc mobility, re-hydration, nutrition delivery, and waste elimination. However, there is insufficient evidence to support the clinical value of the Therapeutic (Wobble) Chair.

Morningstar (2006) stated that lumbar disc herniation is a problem frequently encountered in manual medicine. While manual therapy has shown reasonable success in symptomatic management of these cases, little information is known how manual therapy may affect the structure and function of the lumbar disc itself. In cases where lumbar disc herniation is accompanied by radicular symptoms, electrodiagnostic testing has been used to provide objective clinical information on nerve function. The author examined the treatment rendered for a patient with lower extremity neurological deficit, as diagnosed on electrodiagnostic testing. Patient was treated using spinal manipulation and exercises performed on a Pettibon Wobble Chair, using electrodiagnostic testing as the primary outcome assessment. An elderly male patient presented to a private spine clinic with right-sided foot drop. He had been prescribed an ankle-foot orthosis for this condition. All sensory, motor, and reflex findings in the right leg and foot were absent. This was validated on prior electromyography and nerve conduction velocity testing, performed by a board certified neurologist. Patient was treated using spinal manipulation twice-weekly and wobble chair exercises 3 times daily for 90 days total. Following this treatment, the patient was referred for follow-up electrodiagnostic studies. Significant improvements were made in these studies as well as self-rated daily function. The author concluded that motion-based therapies, as part of a comprehensive rehabilitation program, may contribute to the restoration of daily function and the reversal of neurological insult as detected by electrodiagnostic testing. The author noted that electrodiagnostic testing may be a useful clinical

tool to evaluate the progress of chiropractic patients with lumbar disc herniation and radicular pain syndromes. This was a single case study and findings were confounded by combinational use of spinal manipulation and Pettibon wobble chair.

In contrast to other hands-on modalities, where the practitioner imposes correction on the client through manipulation, the Bowen Technique facilitates the body in healing itself, with minimal intervention. Because of the subtle nature of the Bowen Technique, and the body's continuing response to it over several days thereafter, other forms of manipulative therapy are discouraged for up to 5 days after a session, as they may interfere with the efficacy of the work. However, there is a lack of evidence regarding the effectiveness of the Bowen Technique.

Alcantara et al (2014) stated that constipation compromises the health-related quality of life of children. Chiropractic is a popular alternative therapy for children with constipation. These investigators performed this integrative review of the literature to inform clinical practice. This integrative review of the literature began with an examination of the databases PubMed [1966 to 2013], MANTIS [1964 to 2013] and Index to Chiropractic Literature [1984 to 2013]. The search terms used were "constipation", "chronic constipation", and "bowel dysfunction" in the context of chiropractic. Inclusion criteria involved the care of children 0 to 18 years old published in the English language. These researchers found 14 case reports, 1 case series, and 1 review of the literature. A number of chiropractic techniques were described with treatment varying according to the diagnosis, chief complaint and age of the patient. The authors concluded that this integrative review revealed the need for more research and theoretical development on the care of children with constipation.

Advanced Biostructural Correction is a chiropractic technique that allows for full spinal correction so the body can work the way it was designed to. This approach analyzes and adjusts the spine and body that, over time, allows the body to unwind and recover from its previous injuries and distortions, and thus achieve its optimal, healthy state. This is achieved by first checking for and releasing tension in the meningeal system, followed by adjusting those vertebrae and other bones that the body cannot retrieve or re-position on its own. The Advanced Biostructural

Correction protocol also corrects the forward spinal lean that has been pulling on the brainstem and spinal cord. However, there is a lack of evidence regarding the clinical effectiveness of this approach.

Positional Release Therapy

Kelencz et al (2011) evaluated the treatment of the cervico-brachialgia by Positional Release Therapy (PRT). The present work studied 6 patients aged 44 to 63 (1 male and 5 female) who presented tension in the trapezius upper portion fibers. All patients were submitted to 10 sessions of 30 minutes each. The electromyography (EMG) was collected on the first and 10th day of treatment. The results demonstrated a progressive decrease of pain in each session. The tension was evaluated by the EMG analysis, which showed the relations between time of treatment and less pain. The authors concluded that with these results, it was possible to verify quantitatively the effectiveness of the PRT in the improvement of life quality. This was a small (n = 6), uncontrolled study; its findings need to be validated by well-designed studies.

Ghanbari et al (2012) compared the effectiveness of trigger points' management by PRT and routine medical therapy in treatment of tension type headache (TTH). A total of 30 patients with active trigger points in cervical muscles entered to the study. They were randomly assigned to PRT or medical therapy group. Headache frequency, intensity and duration and tablet count were recorded by use of a daily headache diary. Sensitivity of trigger points was assessed by numeric pain intensity and by use of a digital force gauge (FG 5020). Both groups showed significant reduction in headache frequency and duration and tablet count after treatment phase. However, the reduction of study variables was persisted only in PRT group after follow-up phase. There was no significant reduction in headache intensity, neither in PRT and nor in medication group. Sensitivity of trigger points was significantly reduced. In comparison of the 2 study groups, there was no significant difference in headache frequency, intensity, duration and tablet count ($p > 0.05$). The authors concluded that both procedures were equally effective according to the study. Thus, PRT can be a treatment choice for patients with TTH. The findings of this small study (presumably n = 15 for the PRT group and n = 15 for the medical therapy group) did not provide strong evidence that PRT is effective for the treatment of TTH.

Mohamadi et al (2012) reported the case of a 47-year old female patient with TTH treated by PRT for her trigger points. She had a constant dull headache, which continued all the day for 9 months. A physiotherapist evaluated the patient and found active trigger points in her cervical muscles. Then, she received PRT for her trigger points. After 3 treatment sessions, the patient's headache stopped completely. During the 8 months following the treatment she was without pain, and did not use any medication. The authors concluded that PRT was effective in treating TTH. They stated that these findings suggested that PRT could be an alternative treatment to medication in patients with TTH if the effectiveness of that can be confirmed by further studies.

Alonso-Blanco and colleagues (2012) stated that recent evidence suggested that active trigger points (TrPs) in neck and shoulder muscles contribute to TTH. Active TrPs within the sub-occipital, upper trapezius, sternocleidomastoid, temporalis, superior oblique and lateral rectus muscles have been associated with chronic and episodic TTH. It seems that the pain profile of this headache may be provoked by referred pain from active TrPs in the posterior cervical, head and shoulder muscles. In fact, the presence of active TrPs has been related to a higher degree of sensitization in TTH. Different therapeutic approaches have been proposed for proper TrP management. Preliminary evidence indicated that inactivation of TrPs may be effective for the management of TTH, particularly in a subgroup of patients who may respond positively to this approach. Different treatment approaches targeted to TrP inactivation were discussed in the current paper, focusing on TTH. The authors concluded that new studies are needed to further delineate the relationship between muscle TrP inactivation and TTH.

In a pilot study, Bodes-Pardo et al (2013) determined feasibility of a clinical trial to measure the effects of manual therapy on sternocleidomastoid active TrPs in patients with cervicogenic headache (CeH). A total of 20 patients (7 male and 13 female; mean ± SD age of 39 ± 13 years), with a clinical diagnosis of CeH and active TrPs in the sternocleidomastoid muscle were randomly divided into 2 groups. One group received TrP therapy (manual pressure applied to taut bands and passive stretching), and the other group received simulated TrP therapy (after TrP localization no additional pressure was added, and inclusion of longitudinal stroking but no additional stretching). The primary outcome

was headache intensity (numeric pain scale) based on the headaches experienced in the preceding week. Secondary outcomes included neck pain intensity, cervical range of motion (CROM), pressure pain thresholds (PPT) over the upper cervical spine joints and deep cervical flexors motor performance. Outcomes were captured at baseline and 1 week after the treatment. Patients receiving TrP therapy showed greater reduction in headache and neck pain intensity than those receiving the simulation ($p < 0.001$). Patients receiving the TrP therapy experienced greater improvements in motor performance of the deep cervical flexors, active CROM, and PPT (all, $p < 0.001$) than those receiving the simulation. Between-groups effect sizes were large (all, standardized mean difference, $p > 0.84$). The authors concluded that the findings of this study provided preliminary evidence that a trial of this nature is feasible. The preliminary findings showed that manual therapy targeted to active TrPs in the sternocleidomastoid muscle may be effective for reducing headache and neck pain intensity and increasing motor performance of the deep cervical flexors, PPT, and active CROM in individuals with CeH showing active TrPs in this muscle. They stated that studies including greater sample sizes and examining long-term effects are needed.

In a randomized clinical trial, Llamas-Ramos et al (2014) compared the effects of TrP dry needling (DN) and TrP manual therapy (MT) on pain, function, pressure pain sensitivity, and cervical range of motion in subjects with chronic mechanical neck pain. A total of 94 patients (mean ± SD age of 31 ± 3 years; 66 % female) were randomized into a TrP DN group (n = 47) or a TrP MT group (n = 47). Neck pain intensity (11-point numeric pain rating scale), cervical range of motion (ROM), and pressure pain thresholds (PPTs) over the spinous process of C7 were measured at baseline, post-intervention, and at follow-ups of 1 week and 2 weeks after treatment. The Spanish version of the Northwick Park Neck Pain Questionnaire was used to measure disability/function at baseline and the 2-week follow-up. Mixed-model, repeated-measures analyses of variance (ANOVAs) were used to determine if a time-by-group interaction existed on the effects of the treatment on each outcome variable, with time as the within-subject variable and group as the between-subject variable. The ANOVA revealed that participants who received TrP DN had outcomes similar to those who received TrP MT in terms of pain, function, and cervical ROM. The 4-by-2 mixed-model ANOVA also revealed a significant time-by-group interaction ($p < 0.001$) for PPT:

patients who received TrP DN experienced a greater increase in PPT (decreased pressure sensitivity) than those who received TrP MT at all follow-up periods (between-group differences: post-treatment, 59.0 kPa; 95 % confidence interval [CI]: 40.0 to 69.2; 1-week follow-up, 69.2 kPa; 95 % CI: 49.5 to 79.1; 2-week follow-up, 78.9 kPa; 95 % CI: 49.5 to 89.0). The authors concluded that the results of this clinical trial suggested that 2 sessions of TrP DN and TrP MT resulted in similar outcomes in terms of pain, disability, and cervical ROM. Those in the TrP DN group experienced greater improvements in PPT over the cervical spine. They stated that future trials are needed to examine the effects of TrP DN and TrP MT over long-term follow-up periods.

Preventive or Maintenance Chiropractic Manipulation

Preventive or maintenance chiropractic manipulation has been defined as elective health care that is typically long-term, by definition not therapeutically necessary but is provided at preferably regular intervals to prevent disease, prolong life, promote health and enhance the quality of life. This care may be provided after maximum therapeutic improvement, without a trial of withdrawal of treatment, to prevent symptomatic deterioration or it may be initiated with patients without symptoms in order to promote health and to prevent future problems.

Preventive services may include patient education, home exercises, and ergonomic postural modification. The appropriateness and effectiveness of chiropractic manipulation as a preventive or maintenance therapy has not been established by clinical research and is not covered.

Supportive care has been defined as treatment for patients who have reached maximum therapeutic benefit, but who fail to sustain benefit and progressively deteriorate when there are periodic trials of treatment withdrawal. Continuation of chiropractic care is considered medically necessary until maximum therapeutic benefit has been reached, when the patient fails to progress clinically between treatments, or when pre-injury/illness status has been reached. Once the maximum therapeutic benefit has been achieved, continuing chiropractic care is not considered medically necessary and thus is not covered.

Active corrective care is ongoing treatment, rendered after the patient has become symptomatically and objectively stable, to prevent a recurrence of a patient's condition by correcting underlying abnormal spinal biomechanics that appear to be the cause of the initial injury. The efficacy of active corrective care is not supported by scientific evidence and is not covered.

The Cox Decompression Manipulation/Technique

In a case report, Kruse and Cambron (2011) described a patient with an L5/S1 posterior surgical fusion who presented to a chiropractic clinic with subsequent LBP and leg pain and was treated with Cox decompression manipulation. A 55-year old male postal clerk presented to a private chiropractic practice with complaints of pain and spasms in his low back radiating down the right buttock and leg . His pain was a 5 of 10, and ODI score was 18 %. The patient reported a previous surgical fusion at L5/S1 for a grade 2 spondylolytic spondylolisthesis. Radiographs revealed surgical hardware extending through the pedicles of L5 and S1, fusing the posterior arches. Treatment consisted of ultrasound, electric stimulation, and Cox decompression manipulation (flexion distraction) to the low back. After 13 treatments, the patient had a complete resolution of his symptoms with a pain score of 0 of 10 and an ODI score of 2 %. A 2-year follow-up revealed continued resolution of the patient's symptoms. The authors concluded that the Cox chiropractic decompression manipulation may be an option for patients with LBP subsequent to spinal fusion; more research is needed to verify these results.

In a case report, Joachim (2014) described combined treatment utilizing Cox distraction manipulation and guided rehabilitation for a patient with spine pain and post-surgical C6 to C7 fusion with spondylotic myelopathy and L5 to S1 radiculopathy. A 38-year old man presented to a chiropractic clinic with neck pain and a history of an anterior cervical spine plate fusion at C6 to C7 after a work-related accident 4 years earlier. He had signs and symptoms of spondolytic myelopathy and right lower back, right posterior thigh pain and numbness. The patient was treated with Cox technique and rehabilitation. The patient experienced a reduction of pain on a numeric pain scale from 8/10 to 3/10. The patient was seen a total of 12 visits over 3 months. No adverse effects (AEs) were reported. The author concluded that a patient with a prior C6 to C7

fusion with spondylotic myelopathy and concurrent L5 to S1 radiculopathy improved after a course of rehabilitation and Cox distraction manipulation. Moreover, they stated that further research is needed to establish its effectiveness.

The IntraDiscNutrosis Program

According to the Disc Institute, the IntraDiscNutrosis program is a non-invasive, innovative treatment that can repair seriously damaged discs, providing lasting relief where other treatments have failed.

However, there is a lack of evidence regarding the effectiveness of the IntraDiscNutrosis program.

Management of Menopause-Associated Vasomotor Symptoms

The 2015 position statement of the North American Menopause Society (NAMS) updated and expanded the NAMS evidence-based position on non-hormonal management of menopause-associated vasomotor symptoms (VMS). The North American Menopause Society enlisted clinical and research experts in the field and a reference librarian to identify and review available evidence; 5 different electronic search engines were used to cull relevant literature. Using the literature, experts created a document for final approval by the NAMS Board of Trustees. Non-hormonal management of VMS is an important consideration when hormone therapy is not an option, either because of medical contraindications or a woman's personal choice. Non-hormonal therapies include lifestyle changes, mind-body techniques, dietary management and supplements, prescription therapies, and others. The costs, time, and effort involved as well as AEs, lack of long-term studies, and potential interactions with medications all need to be carefully weighed against potential effectiveness during decision-making. The updated position statement stated that clinicians need to be well-informed about the level of evidence available for the wide array of non-hormonal management options currently available to mid-life women to help prevent underuse of effective therapies or use of inappropriate or ineffective therapies. The North American Menopause Society recommended cognitive-behavioral therapy and, to a lesser extent, clinical hypnosis, which have been shown to be effective in reducing VMS. Paroxetine salt is the only non-hormonal

medication approved by the Food and Drug Administration (FDA) for the management of VMS, although other selective serotonin reuptake/norepinephrine reuptake inhibitors, gabapentinoids, and clonidine showed evidence of efficacy. The NAMS recommended with caution some therapies that may be beneficial for alleviating VMS (e.g., weight loss, mindfulness-based stress reduction, the S-equol derivatives of soy isoflavones, and stellate ganglion block), and noted that additional studies of these therapies are needed. The NAMS did not recommend the following unproven therapies – cooling techniques, avoidance of triggers, exercise, yoga, paced respiration, relaxation, over-the-counter supplements and herbal therapies, acupuncture, calibration of neural oscillations, and chiropractic interventions – because there are negative, insufficient, or inconclusive data regarding the effectiveness of these approaches for managing VMS.

Management of Headaches (e.g., Cervicogenic Headache and Migraine)

Chaibi and colleagues (2015) stated that cervicogenic headache (CEH) is a secondary headache that affects 1.0 to 4.6 % of the population. Although the costs are unknown, the health consequences are substantial for the individual; especially considering that they often suffers chronicity. Pharmacological management has no or only minor effect on CEH. In a single-blinded, placebo-controlled, randomized clinical trial (RCT), these researchers evaluated the effectiveness of chiropractic spinal manipulative therapy (CSMT) for CEH. According to the power calculations, these investigators aimed to recruit 120 participants to the RCT. Participants will be randomized into 1 of 3 groups:

(i) CSMT, (ii) placebo (sham manipulation), and (iii) control (usual non-manual management). The RCT consists of 3 stages: (i) 1 month run-in, (ii) 3 months intervention, and (iii) follow-up analyses at the end of intervention and 3, 6 and 12 months. Primary end-point is headache frequency, while headache duration, headache intensity, headache index (HI) (frequency × duration × intensity) and medicine consumption are secondary end-points. Primary analysis will assess a change in headache frequency from baseline to the end of intervention and to follow-up, where the groups CSMT and placebo and CSMT and control will be compared. Due to 2 group-comparisons, the results with p values

below 0.025 will be considered statistically significant. For all secondary end-points and analyses, the significance level of 0.05 will be used. The results will be presented with the corresponding p values and 95 % CIs. To the authors' knowledge, this is the first prospective manual therapy 3-armed single-blinded placebo-controlled RCT to be conducted for CEH. Current RCTs suggested effectiveness in headache frequency, duration and intensity. However a firm conclusion requires clinical single-blinded, placebo-controlled RCTs with few methodological shortcomings. The present study design adheres to the recommendations for pharmacological RCTs as far as possible and follows the recommended clinical trial guidelines by the International Headache Society.

Chaibi and associates (2017) examined the effectiveness of CSMT for migraineurs. This was a prospective, 3-armed, single-blinded, placebo, RCT of 17 months duration including 104 migraineurs with at least 1 migraine attack per month. The RCT was conducted at Akershus University Hospital, Oslo, Norway. Active treatment consisted of CSMT, whereas placebo was a sham push maneuver of the lateral edge of the scapula and/or the gluteal region. The control group continued their usual pharmacological management. The RCT consisted of a 1-month run-in, 3 months intervention and outcome measures at the end of the intervention and at 3, 6 and 12 months follow-up. The primary end-point was the number of migraine days per month, whereas secondary end-points were migraine duration, migraine intensity and HI, and medicine consumption. Migraine days were significantly reduced within all 3 groups from baseline to post-treatment ($p < 0.001$). The effect continued in the CSMT and placebo group at all follow-up time points, whereas the control group returned to baseline. The reduction in migraine days was not significantly different between the groups ($p > 0.025$ for interaction). Migraine duration and HI were reduced significantly more in the CSMT than the control group towards the end of follow-up ($p = 0.02$ and $p = 0.04$ for interaction, respectively); AEs were few, mild and transient. Blinding was strongly sustained throughout the RCT. The authors concluded that it was possible to conduct a manual-therapy RCT with concealed placebo, and the effect of CSMT observed in this study was probably due to a placebo response.

Moore and colleagues (2017a) evaluated research studies on the prevalence of patient use of manual therapies for the treatment of headache and the key factors associated with this patient population. This critical review of the peer-reviewed literature identified 35 papers reporting findings from new empirical research regarding the prevalence, profiles, motivations, communication and self-reported effectiveness of manual therapy use amongst those with headache disorders. While available data was limited and studies had considerable methodological limitations, the use of manual therapy appeared to be the most common non-medical treatment utilized for the management of common recurrent headaches. The most common reason for choosing this type of treatment was seeking pain relief. While a high percentage of these patients likely continue with concurrent medical care, around 50 % may not be disclosing the use of this treatment to their medical doctor. The authors concluded that there is a need for more rigorous public health and health services research in order to evaluate the role, safety, utilization and financial costs associated with manual therapy treatment for headache. Primary healthcare providers should be mindful of the use of this highly popular approach to headache management in order to help facilitate safe, effective and coordinated care.|

Moore and colleagues (2017b) evaluated the prevalence and characteristics of chiropractors who frequently manage patients with migraine. A national cross-sectional survey of chiropractors collected information on practitioner characteristics, clinical management characteristics and practice settings. A secondary analysis was conducted on 1,869 respondents who reported on their migraine caseload to determine the predictors associated with the frequent management of patients with migraine. A large proportion of chiropractors report having a high migraine caseload (HMC) (n = 990; 53.0 %). The strongest factors predicting a chiropractor having a HMC include the frequent treatment of patients with axial neck pain (odds ratio [OR] = 2.89; 95 % CI: 1.18 to 7.07), thoracic pain (referred/radicular) (OR = 2.52; 95 % CI: 1.58 to 3.21) and non-musculoskeletal disorders (OR = 3.06; 95 % CI: 2.13 to 4.39). The authors concluded that several practice-setting and clinical management characteristics are associated with chiropractors managing a HMC. These findings raised key questions about the therapeutic approach to chiropractic migraine management that deserves further examination. They stated that there is a need for more

primary research to evaluate the approach to headache and migraine management provided by chiropractors and to understand the prevalence, burden and co-morbidities associated with migraine found within chiropractic patient populations.

Treatment of Pregnancy-Related Low Back Pain, Pelvic Girdle Pain, or Combination Pain

In a RCT, Gausel and colleagues (2017) examined the outcome of chiropractic management for a subgroup of pregnant women with dominating one-sided pelvic girdle pain (PGP). The study population was recruited from a prospective longitudinal cohort study of pregnant women. Women reporting pelvic pain (PP), and who were diagnosed with dominating one-sided PGP after a clinical examination, were invited to participate in the intervention study. Recruitment took place either at 18 weeks, or after an SMS-tracking up to week 29. The women were randomized into a treatment group or a control group. The treatment group received chiropractic treatment individualized to each woman with regards to treatment modality and number of treatments. The control group was asked to return to conventional primary health care. The primary outcome measure was new occurrence of full time and/or graded sick leave due to PP and/or LBP. Secondary outcome measures were self-reported PP, physical disability and general health status. Proportion of women reporting new occurrence of sick leave were compared using Chi squared tests. Differences in secondary outcome measures were estimated using linear regression analyses. A total of 56 women were recruited, and 28 of them were randomized into the treatment group, and 28 into the control group. There was no statistically significant difference in sick leave, PP, disability or general health status between the 2 groups during pregnancy or after delivery. The authors concluded that the study did not demonstrate superiority of chiropractic management over conventional care for dominating one-sided PGP during pregnancy. However, the analyses revealed wide confidence intervals containing both positive and negative clinically relevant effects. They stated that further studies on the effect of chiropractic management for specific subgroups of PGP are needed.

In a systematic review, Weis and colleagues (2020) examined the effectiveness of chiropractic care options commonly used for pregnancy-related LBP, PGP, or combination pain for both experienced practitioners and students of chiropractic. These researchers included procedures that were commonly used by chiropractors and not requiring additional certifications. Outcomes were self-reported changes in pain or disability. They used the Scottish Intercollegiate Guideline Network checklists to evaluate outcomes. For strength of evidence, these investigators employed the adapted version of the U.S. Preventive Services Task Force (USPSTF) criteria as described in the United Kingdom report. A total of 50 articles were included from 18 systematic reviews, 30 RCTs, and 2 cohort studies. Pregnancy-related LBP (7 systematic reviews and 12 RCTs): moderate, favorable evidence for electrotherapy and osteopathic manipulative therapy; inconclusive, favorable strength for chiropractic care, exercise, and support devices; and inconclusive, unclear strength for spinal manipulative therapy. Pregnancy-related PGP (4 systematic reviews and 4 RCTs): inconclusive, favorable strength for exercise; and inconclusive, unclear evidence for patient education, information, and support devices. Pregnancy-related LBP or PGP (13 systematic reviews and 12 RCTs): moderate, unclear evidence for complementary and alternative medicine; moderate, unclear evidence for exercise; inconclusive, favorable evidence for multi-modal care, patient education, and physiotherapy; and inconclusive, unclear strength for spinal manipulative therapy, osteopathic manipulative therapy, and support devices. The authors concluded that although there is a lack of conclusive evidence, many of the interventions had moderate or unclear but favorable evidence.

Furthermore, an UpToDate review on “Maternal adaptations to pregnancy: Musculoskeletal changes and pain” (Bermas, 2021) states that “A systematic review of eight trials on complementary and alternative medicine for low back pain and/or pelvic pain in pregnancy reported reduced visual analog pain scores for patients treated with acupuncture based on three trials. However, variations in the duration of treatment, gestational age at treatment, and control groups limit the ability to make definitive conclusions or practice recommendations. In the same systematic review, osteopathy and chiropractic modalities were not associated with pain reduction, but the data were based on one trial for each treatment group”.

Other Experimental, Investigational, or Unproven Indications of Chiropractic

Saleh and associates (2015) stated that chiropractic is a complementary medicine that has been growing increasingly in different countries over recent decades. It addresses the prevention, diagnosis and treatment of the neuro-musculoskeletal system disorders and their effects on the whole body health. These investigators evaluated the effectiveness of chiropractic in the treatment of different diseases. They searched scientific electronic databases (e.g., Cochrane, Medline, Google Scholar, and Scirus) and all systematic reviews in the field of chiropractic were obtained. Reviews were included if they were specifically concerned with the effectiveness of chiropractic treatment, included evidence from at least 1 clinical trial, included randomized studies and focused on a specific disease. The research data including the article's first author's name, type of disease, intervention type, number and types of research used, meta-analysis, number of participants, and overall results of the study, were extracted, studied and analyzed. A total of 23 chiropractic systematic reviews were found, and 11 articles met the defined criteria. The results showed the influence of chiropractic on improvement of neck pain, shoulder and neck trigger points, and sport injuries. In the cases of asthma, autism spectrum disorder, back pain, carpal tunnel syndrome, fibromyalgia, gastro-intestinal problems, and infant colic, there was no conclusive scientific evidence. The authors concluded that there is heterogeneity in some of the studies and also limited number of clinical trials in the assessed systematic reviews; conducting comprehensive studies based on more reliable study designs are highly recommended.

Infant Colic

Carnes and colleagues (2018) carried out a systematic review and meta-analyses to examine the effect of manual therapy for healthy but unsettled, distressed and excessively crying infants and to provide information to help clinicians and parents to make informed-decisions regarding care. These investigators reviewed published peer-reviewed primary research articles in the last 26 years from 9 databases (Medline Ovid, Embase, Web of Science, Physiotherapy Evidence Database, Osteopathic Medicine Digital Repository , Cochrane (all databases), Index of Chiropractic Literature, Open Access Theses and Dissertations

and Cumulative Index to Nursing and Allied Health Literature). The inclusion criteria were: manual therapy (by regulated or registered professionals) of unsettled, distressed and excessively crying infants who were otherwise healthy and treated in a primary care setting. Outcomes of interest were: crying, feeding, sleep, parent-child relations, parent experience/satisfaction and parent-reported global change. A total of 19 studies were selected for full review: 7 RCTs, 7 case-series studies, 3 cohort studies, 1 service evaluation study and 1 qualitative study. They found moderate strength evidence for the effectiveness of manual therapy on: reduction in crying time (favorable: -1.27 hours per day (95 % CI: -2.19 to -0.36)), sleep (inconclusive), parent-child relations (inconclusive) and global improvement (no effect). The risk of reported adverse events (AEs) was low: 7 non-serious events per 1,000 infants exposed to manual therapy (n = 1,308), and 110 per 1,000 in those not exposed. The authors concluded that they found moderate favorable evidence for the reduction in crying time in infants receiving manual therapy care (around 1 hour per day), but this may change with further research evidence. These investigators still do not know if this result is meaningful to parents or if the reduction is due to the manual therapy component of care or other aspects of care. For other outcomes, the strength of evidence was low and inconclusive. Moreover, these researchers stated that the outcomes for parental satisfaction and confidence were under-researched, and they did not find much data about these. Collecting parent outcomes may provide more informative data about the active components of care. They stated that a well-powered RCT with parental blinding, blinded assessment of reported outcomes, testing both non-specific and manual therapy effects of manual therapist care is needed to supplement research in this area.

The authors stated that this study had 2 drawbacks. First, there was 1 Chinese paper that was selected for full paper review. These investigators translated this article, but they were unable to fully interpret and understand the treatment given and the outcomes that related to Chinese Traditional Medicine energy points. In other words, the therapeutic paradigm presented was beyond the authors' knowledge from a Western medicine perspective. Second, inclusion criteria were specific to this population of interest (i.e., thriving infants who were inexplicably unsettled, distressed and excessively crying who were treated in primary care). This symptom-based approach to selection allowed the inclusion

of studies relating to various diagnoses (e.g., breast-feeding, gastric and behavioral problems). However, this latitude could also be interpreted as a weakness, since definitions of unsettledness, distress and excessive crying and otherwise healthy were not always clear. Perhaps a more stringent, universally accepted definition of "colic" is needed. Thus, these researchers may have failed to include some studies due to the authors' descriptions of their populations.

Chiropractic Management of Depression

Chu and Ng (2018) reported the case of a 44-year old school teacher who experienced long-term relief from tension-type headache (TTH) and major depression following chiropractic treatment. It is well-recognized that psychiatric co-morbidity and suicide risk are commonly found in patients with painful physical symptoms such as chronic headache, backache, or joint pain. Recent studies indicated that autonomic dysfunction plays a role in the pathogenesis of TTHs and depressive disorders. The autonomic nervous system is mainly controlled by reflex centers located in the spinal cord, brain stem, and hypothalamus. This report high-lighted the rewarding outcomes from spinal adjustment in certain neuropsychiatric disorders. The authors concluded that long-term results of chiropractic adjustment in this particular case were very favorable. Moreover, they stated that further studies with larger groups are needed to better clarify the role of chiropractic.

Chiropractic Management of Dizziness/Vertigo

Kendall and colleagues (2018) noted that dizziness in the elderly is a risk factor for falls. Neck pain is associated with dizziness and responds favorably to neck manipulation. However, it is unknown if chiropractic intervention including instrument-assisted manipulation of the neck in the elderly with neck pain could also improve dizziness. This parallel 2-arm pilot trial was conducted in Melbourne, Australia over 9 months (October 2015 to June 2016). Participants aged 65 to 85 years, with self-reported chronic neck pain and dizziness, were recruited from the general public through advertisements in local community newspapers and via Facebook. Participants were randomized using a permuted block method to 1 of 2 groups: Activator II-instrument-assisted cervical and thoracic spine manipulation plus a combination of: light massage; mobilization;

ROM exercises; and home advice about the application of heat, or Sham-Activator II-instrument-assisted manipulation (set to zero impulse) plus gentle touch of cervical and thoracic spinal regions. Participants were blinded to group allocation. The interventions were delivered weekly for 4 weeks. Assessments were conducted 1 week pre- and post-intervention. Clinical outcomes were assessed blindly and included: dizziness (dizziness handicap inventory [DHI]); neck pain (neck disability index [NDI]); self-reported concerns of falling; mood; physical function; and treatment satisfaction. Feasibility outcomes included recruitment rates, compliance with intervention and outcome assessment, study location, success of blinding, costs and harms. Out of 162 enquiries, 24 participants were screened as eligible and randomized to either the chiropractic (n = 13) or sham (n = 11) intervention group. Compliance was satisfactory with only 2 participants lost to follow-up; thus, post-intervention data for 12 chiropractic intervention and 10 sham intervention participants were analyzed; blinding was similar between groups. Mild harms of increased spinal pain or headaches were reported by 6 participants. Costs amounted to AUD$ 2,635 per participant. The data showed a trend favoring the chiropractic group in terms of clinically-significant improvements in both NDI and DHI scores. Sample sizes of n = 150 or n = 222 for dizziness or neck pain disability as the primary outcome measure, respectively, would be needed for a fully powered trial. The authors concluded that recruitment of participants in this setting was difficult and expensive. However, a larger trial may be feasible at a specialized dizziness clinic within a rehabilitation setting. Compliance was acceptable and the outcome measures used were well accepted and responsive.

Furthermore, an UpToDate review on "Treatment of vertigo" (Furman and Barton, 2018) does not mention chiropractic / spinal manipulation as a therapeutic option.

Chiropractic Management of Female Infertility

Budgell and Yee (2018) noted that debate concerning chiropractic management of female infertility occurs largely in the absence of reference to the extant literature. These investigators carried out a scoping review of primary data publications on the chiropractic management of female infertility based on searches of the Index to

Chiropractic Literature and PubMed, supplemented by papers from one author's archive. A total of 10 articles, all case studies, met the review's inclusion criteria and documented the experiences of 11 women (mean age of 31 years; mean period of infertility 3 years). Pregnancy occurred, on average, after 5 months of treatment with spinal manipulation and adjunctive modalities. No adverse events (AEs) were reported. There are very few original data articles documenting responses of infertile females treated with spinal manipulation. The authors concluded that in the absence of a robust body of primary data literature, the use of spinal manipulation for the management of female infertility should be approached with caution.

Furthermore, an UpToDate review on "Treatments for female infertility" (Kuohung and Hornstein, 2018) does not mention chiropractic / spinal manipulation as a therapeutic option.

The NUCCA Procedure

According to the National Upper Cervical Chiropractic Association, the NUCCA procedure frees the nervous system of interference by using a precise, non-invasive, gentle touch technique. The NUCCA procedure brings several generations of clinical research to correcting the serious problem of the atlas subluxation complex. By using precise and objective x-ray views of the head and neck, mathematical measurement and analysis are made of the misalignment. Once the misalignment is understood by the doctor, there is no need for further x-rays because correlating the relationship between posture and upper cervical misalignment allows posture to then be used thereafter to judge alignment. There is also often less need for repeated corrections because returning the bones of the neck to a normal position also normalizes function in the body. To begin, most doctors offer a consultation so that you can experience the office and make sure the people and process are a comfortable match to your needs. This gives the doctor a chance to hear a bit about your situation, make some measurements, and discuss the potential of NUCCA treatment. The supine leg check, which shows leg length inequality, is the basic standard to determine if you have an upper cervical misalignment. Many doctors use an Anatometer, a NUCCA endorsed measuring tool that evaluates standing posture. Some doctors may use other devices including the

Gravity Stress Analyzer and hip calipers. Any other health problems, injuries, motor vehicle accidents, surgeries, along with other treatment programs, which include diagnostic tests and x-rays, are also evaluated and assessed. After this initial process, the doctor will begin the steps necessary in determining if your spinal column is significantly misaligned or out of balance.

There is insufficient evidence to support the use of the NUCCA procedure for the management of various health conditions.

Bakris et al (2007) noted that anatomical abnormalities of the cervical spine at the level of the Atlas vertebra are associated with relative ischemia of the brainstem circulation and increased blood pressure (BP). Manual correction of this mal-alignment has been associated with reduced arterial pressure. This pilot study tested the hypothesis that correcting mal-alignment of the Atlas vertebra reduces and maintains a lower BP. Using a double blind, placebo-controlled design at a single-center, 50 drug naïve (n = 26) or washed out (n = 24) patients with Stage 1 hypertension were randomized to receive a National Upper Cervical Chiropractic (NUCCA) procedure or a sham procedure. Patients received no anti-hypertensive meds during the 8-week study duration. The primary end-point was changed in systolic and diastolic BP comparing baseline and week 8, with a 90 % power to detect an 8/5 mm Hg difference at week 8 over the placebo group. The study cohort had a mean age 52.7 +/- 9.6 years, consisted of 70 % men. At week 8, there were differences in systolic BP (-17 +/- 9 mm Hg, NUCCA versus -3 +/- 11 mm Hg, placebo; $p < 0.0001$) and diastolic BP (-10 +/- 11 mm Hg, NUCCA versus -2 +/- 7 mm Hg; $p = 0.002$). Lateral displacement of Atlas vertebra (1.0, baseline versus 0.04 degrees week 8, NUCCA versus 0.6, baseline versus 0.5 degrees , placebo; $p = 0.002$). Heart rate was not reduced in the NUCCA group (-0.3 beats/min, NUCCA, versus 0.5 beats/min, placebo). No adverse effects (AEs) were recorded. The authors concluded that restoration of Atlas alignment was associated with marked and sustained reductions in BP similar to the use of 2-drug combination therapy.

The authors stated that this pilot study had limitations including the fact that it was dependent on the skill of one practitioner to do the manipulation. It was designed, however, to test the concept that non-

surgical manipulation could alleviate elevations in BP, thus it could not be generalized until confirmed in a larger trial, which is being planned.

Westersund et al (2017) stated that clinical observation and anecdotal reports suggested changes could occur to dental occlusion following intervention with the NUCCA procedure. This case-controlled study discerned if occlusion changes are measurable using a dental force plate (T-Scan) following an adjustment to the cranio-cervical junction (CCJ). A degree of case control was established by active patients being assessed twice prior to and following intervention. Before-after intervention assessment included posture evaluation and dental occlusion (T-Scan). Findings suggested that changes in posture and occlusion could be observed after the NUCCA chiropractic procedure. Not all patients demonstrated a more balanced contact pattern following the adjustment, indicating a need for further investigation. The authors concluded that these findings may suggest interconnectivity between the CCJ and an individual's occlusal contacts and support the need for further integration between chiropractors and dentists seeking to co-manage temporo-mandibular joint (TMJ) disorders.

Furthermore, the Washington State Chiropractic Commission (2014) did not endorse the National Upper Cervical Chiropractic Association (NUCCA) procedure as an adjustive technique.

Improvement of Brain Function

Meyer and colleagues (2019) noted that a recent hypothesis purports that spinal manipulation may cause changes at a brain level. Functional neurology, a mainly chiropractic approach, promotes the use of spinal manipulation to improve "brain function" as if it were a proven construct. No systematic review has been performed to investigate how well founded this hypothesis is. In this systematic review, these researchers examined if spinal manipulation has an effect on "brain function" that is associated with any clinical benefits. They carried out a literature searched in PubMed, Embase, and PEDro (final search in February 2018). These investigators included RCTs or non-RCTs, in which spinal manipulation was performed to any region of the spine, applied on either symptomatic or asymptomatic individuals, and compared to a sham or to another type of control. The outcome measures had to be stated as

direct or proxy markers of "brain function". Studies were reviewed blindly by at least 2 reviewers, using a quality check-list designed for the specific needs of the review. Studies were classified as of "acceptable", "medium", or '"ow" methodological quality. Results were reported in relation to control intervention (sham, "inactive control", or "another physical stimulus"); and study subjects (healthy, symptomatic, or with spinal pain "subjects/spinal pain"), taking into account the quality. Only results obtained from between-group or between-intervention comparisons were considered in the final analysis. A total of 18 of 1,514 articles were included. Studies were generally of "low" or "medium" methodological quality, most comparing spinal manipulation to a control other than a sham; 13 out of the 18 studies could be included in the final analysis. Transitory effects of different types of "brain function" were reported in the 3 studies comparing spinal manipulation to sham (but of uncertain credibility), in "sub-clinical neck/spinal pain" subjects or in symptomatic subjects. None of these 3 studies, of "medium" or "acceptable" quality, examined if the neurophysiological effects reported were associated with clinical benefits. The remaining 10 studies, generally of "low" or "medium" quality, compared spinal manipulation to "inactive control" or "another physical stimulus" and similarly reported significant between-group differences but inconsistently. The authors concluded that the available evidence suggested that changes occurred in "brain function" in response to spinal manipulation but were inconsistent across and sometimes within studies. These researchers stated that the clinical relevance of these changes is unknown; thus, It is premature to promote the use of spinal manipulation as a treatment to improve "brain function".

Rheumatic Diseases

In a systematic review, Phang and colleagues (2018) summarized all good quality RCTs using CAM interventions in patients with rheumatic diseases. These researchers carried out a literature review guided by the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA). They excluded non-English language articles and abstract-only publications. Due to the large number of RCTs identified, these investigators only included "good quality" RCTs with Jadad score of 5. They identified 60 good quality RCTs using CAM as intervention for patients with rheumatic diseases: acupuncture (n = 9), Ayurvedic

treatment (n = 3), homeopathic treatment (n = 3), electricity (n = 2), natural products (n = 31), mega-vitamin therapies (n = 8), chiropractic or osteopathic manipulation (n = 3), and energy healing therapy (n = 1). The studies did not appear to suggest a particular type of CAM was effective for all types for rheumatic diseases. However, some CAM interventions appeared to be more effective for certain types of rheumatic diseases. Acupuncture appeared to be beneficial for osteoarthritis (OA), but not rheumatoid arthritis (RA). For the other therapeutic modalities, the evidence base either contained too few trials or contains trials with contradictory findings that precluded any definitive summary. There were only minor adverse reactions observed for CAM interventions presented. The authors identified 60 good quality RCTs that were heterogenous in terms of interventions, disease, measures used to evaluate outcomes, and efficacy of CAM interventions. Evidence indicated that some CAM therapies may be useful for rheumatic diseases, such as acupuncture for OA. These researchers stated that further research with larger sample size is needed for more conclusive evidence regarding the efficacy of CAM interventions for the management of patients with rheumatic diseases.

Chiropractic BioPhysics Methods for the Treatment of Lumbar Lordosis and/or Low Back Disorders

In a systematic review, Oakley and colleagues (2020) examined controlled trial evidence for the use of lumbar extension traction by Chiropractic BioPhysics methods for increasing lumbar lordosis in those with hypo-lordosis and low back disorders. These investigators carried out literature searches in PubMed, PEDro, CINAHL, Cochrane, and ICL data-bases. Search terms included iterations related to the lumbar spine, LBP and extension traction rehabilitation. A total of 4 articles detailing 2 randomized and 1 non-randomized trial were located. Trials demonstrated increases in radiographic measured lordosis of 7 to 11°, over 10 to 12 weeks, after 30 to 36 treatment sessions. Randomized trials demonstrated traction treated groups mostly maintained lordosis correction, pain relief, and disability after 6-months follow-up. The non-randomized trial showed lordosis and pain intensity were maintained with periodic maintenance care for 1.5 years. More importantly, control/comparison groups had no increase in lumbar lordosis. Randomized trials showed comparison groups receiving physiotherapy-

less the traction, had temporary pain reduction during treatment that regressed towards baseline levels as early as 3 months after treatment. The authors concluded that limited but good quality evidence substantiated that the use of extension traction methods in rehabilitation programs definitively increased lumbar hypo-lordosis. Moreover, these researchers stated that preliminarily, these studies showed these methods provide longer-term relief to patients with low back disorders versus conventional rehabilitation approaches tested. They stated that future studies testing lumbar extension traction methods are needed for a more adequate understanding of this new important treatment procedure, including but not limited to older and younger patient populations.

The authors stated that due to the limited number of studies, the conclusions from this review are preliminarily. Another drawback was that the measurement method for lumbar lordosis across the studies had slight variation (e.g., L1 to L5 absolute rotation angle [ARA]) versus L1 to L5 Cobb angle versus T12 to S1 ARA; despite this, the significant improvements in lumbar extension traction treatment groups were reported within each trial. In addition, the population groups studied were all similar, mid-aged adults (average ages of 39 to 46 years). Although limited, there was good quality evidence that indicated increasing the lumbar lordosis via extension traction as part of multi-modal rehabilitation programs were associated with superior outcomes over "standard-care" treatment programs that did not improve hypo-lordosis. These researchers stated that future studies are needed to overcome the limitations identified and improve the understanding of lumbar extension traction methods discussed in this review. For example, a study seeking to identify the optimum subgroup of patient lumbar curvatures that will respond to lumbar extension traction as they relate to initial pelvic morphology values is needed. Second, a study examining multiple programs of lumbar extension traction applications is needed; in this way the optimum dose response over time can be identified for those patients who improve but still remain with pain, disability, and loss of curvature. Third, an RCT with a cross-over design is needed in order to more accurately identify that patients receiving lumbar extension traction applications for lumbar hypo-lordosis are the ones who indeed have the optimum improvement for their back pain and related disabilities.

Chiropractic Care for the Treatment of Postpartum-Related Low-Back Pain, and/or Pelvic Girdle Pain

In a systematic review, Weis and colleagues (2020) (SR) examined the effectiveness of specific chiropractic care options commonly used for postpartum-related LBP, PGP, or combination (LBP and PGP) pain. Interventions were those manual or other non-pharmacologic therapies commonly used by chiropractors (not requiring additional certifications). The outcomes were self-reported changes in pain or disability self-reported outcomes. These investigators used the Scottish Intercollegiate Guideline Network check-lists. Strength of the evidence (excluding cohort studies) was determined using an adapted version of the U.S. Preventive Services Task Force criteria as described in the U.K. report. Of the 1,611 published articles, 16 were included. These were 5 systematic reviews, 10 RCTs, and 1 cohort study. Postpartum-related LBP (1 RCT): moderate, favorable strength for spinal manipulation therapy/mobilization. Postpartum-related PGP (4 RCTs): moderate, unclear strength for exercise; and inconclusive, unclear strength for patient education. Postpartum-related LBP or PGP (3 systematic reviews and 4 RCTs): inconclusive, unclear strength for exercise, self-management, and physiotherapy; while osteopathic manipulative therapy was inconclusive, favorable. The authors concluded that no therapeutic option was identified as having sufficient evidence to make a clear recommendation. This systematic review identified a scarcity of literature regarding chiropractic care and back pain for postpartum women, as well as inconsistency among the terms LBP, PGP, and combination pain. These researchers stated that the findings of this systematic review demonstrated the need for higher-quality and more robust studies in this population.

Combined Chiropractic and Acupuncture for the Treatment of Cervical Spondylosis Radiculopathy

Wang and colleagues (2020) stated that the pathogenesis of cervical spondylosis is degenerative changes of the cervical intervertebral disc, or bone hyperplasia of the posterior and hook joints, and instability of the joints of the cervical vertebrae. It causes the nerve roots to be stimulated and oppressed. The clinical manifestations are the sensation, movement, and reflex disorder of the cervical spinal nerve roots that are stimulated

and oppressed, especially numbness and pain of the neck, shoulders, and upper extremities. In a systematic review, these investigators aimed to examine the safety and efficacy of combined chiropractic and acupuncture in the treatment of cervical spondylosis radiculopathy. They will search for PubMed, Cochrane Library, AMED, Embase, WorldSciNet, Nature, Science online and China Journal Full-text Database (CNKI), China Biomedical Literature CD-ROM Database (CBM), and related RCTs included in the China Resources Database. The time is limited from the construction of the library to September 2019. These researchers will use the criteria provided by Cochrane 5.1.0 for quality assessment and risk assessment of the included studies, and use the RevMan 5.3 and Stata 13.0 software for meta-analysis of the effectiveness, recurrence rate, and symptom scores of cervical spondylosis radiculopathy. The authors noted that this systematic review will examine the safety and efficacy of combined chiropractic and acupuncture for the treatment of cervical spondylosis radiculopathy. They stated that the results of this study may provide a possible ranking for acupuncture and chiropractic treatment of cervical spondylosis radiculopathy.

Chiropractic for the Management of Axial Spondyloarthritis

Deodhar and colleagues (2022) noted that diagnosis of axial spondyloarthritis (axSpA) is often associated with chronic inflammatory back pain (IBP) and frequently occurs years after initial onset of clinical symptoms. Recognition of IBP is important for timely referral of patients with suspected axSpA to a rheumatologist. Patients with all types of back pain are treated in chiropractic care; however, the proportion of patients with undiagnosed axSpA is unknown. In a systematic review, these investigators examined the presence of axSpA in patients treated by chiropractors and identified the chiropractor's role in axSpA diagnosis, referral, and management. They carried out a PubMed search using the following search strings: "chiropract*" AND ("sacroiliac" OR "back pain" OR "spondyloarthritis" OR "ankylosing spondylitis"); English language, since 2009; and (chiropractic OR chiropractor) AND (ankylosing spondylitis OR axial spondyloarthritis), with no date limits. Of 652 articles identified in the searches, 27 met the inclusion criteria. Although back pain was identified as a common reason for patients seeking chiropractic care, there was no mention of axSpA, ankylosing spondylitis, or the

distinction between mechanical and IBP. Data from relevant articles suggested that the majority of patients seeking chiropractic care have LBP, whereas no articles reported axSpA in this patient population. The authors concluded that the near absence of any identified articles on axSpA in chiropractic care may be due to under-recognition of axSpA, resulting in delayed rheumatology referral and appropriate management. They stated that better awareness and increased use of validated screening tools could reduce diagnostic delay of axSpA in chiropractic care.

Furthermore, an UpToDate review on "Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults" Yu and van Tubergen, 2021) states that "Spinal manipulation should be avoided in patients with spinal fusion or advanced spinal osteoporosis".

Chiropractic Biophysics Technique / Chiropractic BioPhysics Methods

In a single-case report, Kallan et al (2022) showed the reduction of lumbar hyper-lordosis, sacral base angle and anterior thoracic translation posture in an 11-year-old girl. Subject presented with lumbar hyper-lordosis and underwent CBP treatment protocols to reduce her spinal deformity and correlated symptoms. Symptoms included thoracolumbar, hip, knee and ankle pains and lower extremity weakness. Radiographs confirmed lumbar hyper-lordosis, increased sacral base angle and a forward translated thoracic posture. Spinal traction as well as corrective exercises and spinal manipulative therapy was carried out over an 11-month period. After 57 treatments, there was a 13.4° reduction in L1 to L5 lordosis, an 11.8° reduction in sacral base angle and a 13.8 mm reduction in anterior thoracic translation. The improved structural changes correlated with improved symptoms. The authors concluded that lumbar hyper-lordosis could be reduced in pediatric patients presenting with hyper-lordosis and associated symptomatology. Routine radiography may be needed in the diagnosis of lumbar spine deformities in pediatrics. Moreover, these investigators stated that further research into the non-surgical reduction of lumbar spine hyper-lordosis is needed.

The authors stated that main drawback of this study was that it was a single-case study. The similarity of structural correction in this case as compared to the few other reports documenting non-surgical reduction in lumbar hyper-lordosis showed promise that CBP methods employed to reduce lumbar hyper-lordosis may be equally effective in adults and children. In fact, one issue that needs to be unveiled is what standard treatment protocol needs to be adopted for children versus adults in the application of CBP methods considering their unique differences (i.e., flexibility, etc.). These investigators stated that further research is needed for all age groups.

Chiropractic Manipulation for the Prevention of Fall

Grabowska et al (2022) stated that falls in the elderly are a significant and growing public health concern. There are multiple risk factors associated with falls that may be addressed within the scope of chiropractic training and licensure. Few attempts have been made to summarize existing evidence on multi-modal chiropractic care and fall risk mitigation. In a systematic review , these investigators summarized this research to-date. They carried out a systematic review according to the PRISMA guidelines. Databases searched included PubMed, Embase, Cochrane Library, PEDro, and Index of Chiropractic Literature. Eligible study designs included RCTs, prospective non-randomized controlled, observational, and cross-over studies in which multi-modal chiropractic care was the primary intervention and changes in gait, balance and/or falls were outcomes. Risk of bias was also evaluated using the 8-item Cochrane Collaboration Tool. The original search yielded 889 articles; 21 met final eligibility including 10 RCTs. One study directly measured the frequency of falls (under-powered secondary outcome) while most studies examined short-term measurements of gait and balance. The overall methodological quality of identified studies and findings were mixed, limiting interpretation regarding the potential impact of chiropractic care on fall risk to qualitative synthesis. The authors concluded that little high-quality research has been published to inform how multi-modal chiropractic care could best address and positively influence fall prevention. These researchers proposed strategies for building an evidence base to examine the role of multi-modal chiropractic care in fall prevention and outline recommendations for future research to fill current

evidence gaps. Moreover, these investigators stated that future research on falls and mobility represents both an exciting area of contribution for the chiropractic profession and a critical topic for public health.

The authors stated that this study had several drawbacks. First, only studies in the English language were included, the search strategy was developed without formal help from a librarian, and a protocol was not developed or registered a priori. Second, based on the limited evidence to-date, only a small number of studies met the inclusion and exclusion criteria. Third, there was a great deal of heterogeneity across the included studies in terms of study design characteristics, methodologic quality, demographics of subjects, interventions, outcomes, and settings, excluding the possibility of quantitative synthesis with meta-analysis, and significantly constraining narrative synthesis. Of note, the majority of included studies were small pilot studies, with overall low methodological quality. As a whole, this heterogeneity and low methodological quality limited the conclusions that can be drawn from these data. Fourth, the inclusion criteria targeted studies that included evaluations of components of multi-modal chiropractic care (e.g., spinal manipulation, and myofascial therapies), as delivered by a doctor of chiropractic (DC). Some of these modalities were also delivered by other professions (e.g., osteopath, physical therapist), and because of the limits of the search strategy, these findings could not distinguish chiropractic-specific impacts of the included interventions compared to the impacts of these interventions as delivered by other professions.

Chiropractic Manipulation for the Treatment of Post-Concussion Syndrome

Masarsky (2018) noted that hypopituitarism diagnosed months or years following concussive injury can cause a variety of endocrine disturbances including insufficient secretion of human growth, luteinizing, follicle stimulating, thyroid stimulating, adrenocorticotrophic, and anti-diuretic hormones (GH, LH, FSH, TSH, ACTH, and ADH). Recent evidence suggested that autoimmune reactions against pituitary and/or hypothalamic tissue constitute an etiologic factor for this hypopituitarism. One important trigger for autoimmunity is hypoxic stress. This trigger may be especially important in the post-concussive brain, which is particularly vulnerable to hypoxic stress. The vulnerable vasculature of

the hypothalamic infundibulum can be a source of local exacerbation of any systemic hypoxia. Taking the above into account, it appeared reasonable to hypothesize that hypoxic stress is a risk factor for post-concussive hypopituitarism. Following a discussion of literature relevant to this hypothesis, these researchers suggested retrospective and prospective research methods for testing the hypothesis. Retrospective methods for hypothesis testing include comparing post-concussion victims with and without evidence of hypopituitarism in terms of their history of respiratory problems such as smoking, exposure to indoor and outdoor air pollution, chronic obstructive pulmonary disease (COPD), asthma, obstructive sleep apnea (OSA), and opioid use or abuse. Significantly greater incidence of respiratory history among the hypopituitarism patients would support the hypothesis. Prospective methods include performing detailed respiratory history and examination immediately post-injury, then performing periodic endocrine panels to detect hypopituitarism during long-term follow-up. The hypothesis will be supported if development of hypopituitarism among patients with positive respiratory history or examination findings post-injury is more frequent than hypopituitarism among concussion victims with negative respiratory history and examination findings. If the hypothesis is supported, effective prevention of post-concussive hypopituitarism should include efforts to support optimal respiratory function. Such efforts may be relevant to treatment as well. These efforts would include respiratory therapy, smoking cessation, treatment of OSA, prudent stepping down of opioid use, incentive spirometry, aerobic exercise, and other conventional measures as indicated. Non-Western measures such as yoga should be considered as well. Furthermore, chiropractic care as an intervention that may ameliorate hypoxia at the systemic and local levels was discussed. These researchers stated that it is worth mentioning the literature that suggested chiropractic adjustments could alleviate reflex sympathetic dystrophy. While these cases did not involve the pituitary as such, the normalization of vasomotor tone suggested that chiropractic adjustments may also alleviate vasoconstriction at the infundibular choke point of the hypothalamus. This would tend to alleviate hypoxic stress at the local tissue level. Taking all of the above into account, if the hypoxic stress hypothesis of post-concussive hypopituitarism is supported, the objective of prevention would best be served by an integrative health care approach including chiropractic and all other relevant practices. Such an approach has recently been advocated by Cohen et al in relation to care

of the cardiovascular patient. This study did not provide any clinical data regarding the effectiveness of chiropractic for the treatment of post-concussion syndrome (PCS).

In a case-series study, Germann et al (2020) described the multi-modal treatment plans delivered by 2 chiropractic sports specialists for the management of PCS. A total of 3 concussion cases were presented each with different mechanisms of injury (2 sport-related and 1 non-sport-related) and each within a different stage of recovery (acute, sub-acute, and chronic). Treatment plans included patient education, sub-symptom threshold exercise, soft-tissue therapy, spinal manipulation, and cervical spine as well as visual/vestibular rehabilitation exercises. This series highlighted 3 important observations: First, the effectiveness of individualized, multi-modal treatment plans based on suggested clinical profiles for patients with PCS of various stages. Second, the delineation of concussion literature based on mechanism of injury (i.e., sport- versus non-sport-related) may be unnecessary. Third, these cases provided encouraging evidence to support the inclusion of manual therapists with advanced knowledge of concussion treatment, such as chiropractors, as part of the inter-disciplinary healthcare team when managing patients with PCS. The authors concluded that emerging research suggested that patients diagnosed with PCS, regardless of the mechanism of injury, can be characterized by 1 or more clinical profiles based on their clinical assessment. These clinical profiles can then guide the development of individualized, multi-modal treatment plans that can significantly improve patients' symptoms. There is limited evidence describing the role that chiropractic sport specialists may play in the inter-disciplinary management of concussion outside of sport. This case series described 3 individualized multi-modal treatment plans delivered by sports chiropractors that included sub-symptomatic threshold exercise, vestibulo-ocular rehabilitation, spinal manipulation, soft-tissue therapy, and dietary modification during the management of both sport and non-sport related concussion. The positive results from this case series further contribute to the evolving literature supporting the role of chiropractors in the primary management of concussive symptoms of various origin and duration.

The authors stated that this case series had several drawbacks. First, the absence of original diagnostic imaging and laboratory reports for Case 3. During this time the patient relocated and changed family physicians and was not able to obtain copies of these investigations. These diagnostic reports would aid in describing the breadth of evaluations the patient in Case 3 had undergone and would emphasize the difficulty experienced in previous attempts at managing this case. Second, results from a baseline post-concussion-symptom scale (PCSS) score in Cases 1 and 3, and a final follow-up PCSS score in Case 2 would provide reference upon which one could better judge the extent of the patients' recovery. Although the patient in Case 3 reported the continuation of 3 low-level symptoms at the point of discharge, it has been noted that both healthy controls and those with other co-morbidities reported the presence of various non-specific symptoms that are also commonly experienced by those with PCS. Thus, one was unable to determine whether or not the patient would have reported these symptoms on a baseline PCSS even before her injury. Such a situation was well demonstrated by the baseline PCSS results of the patient in Case 2. Third, the use of a multi-modal treatment plan created a challenge when trying to determine which intervention is providing therapeutic benefit to the patient. Fourth, although the recovery outcomes were positive in each of the 3 cases in this series, it should be noted that there were inherent limitations in the generalizability of case series results to other concussed patients. Fifth, the concept of "clinical profiles / domains" is still an emerging theory, and it is uncertain at what time during recovery these clinical profiles become important with respect to treatment outcomes. These researchers stated that additional research on the use of impairment-based, multi-modal treatment plans, along with the timing for which such a plan should be implemented is needed.

Rytter et al (2021) stated that persistent (greater than 4 weeks) post-concussion symptoms (PPCS) are challenging for both patients and clinicians. There is uncertainty regarding the effect of commonly applied non-pharmacological treatments for the management of PPCS. These investigators systematically examined evidence for outcomes related to 7 non-pharmacological interventions for PPCS in adults (aged greater than 18 years) and provided recommendations for clinical practice. They carried out a systematic literature searches via Embase, Medline,

PsycINFO, CINAHL, PEDro, OTseeker, and Cochrane Reviews (via Medline and Embase) from earliest possible publication year to March 3, 2020. The literature was searched for prior systematic reviews and primary studies. To be included, studies had to be intervention studies with a control group and focus on PPCS. A multi-disciplinary guideline panel selected interventions based on frequency of use and need for decision support among clinicians, including early information and advice, graded physical exercise, vestibular rehabilitation, manual treatment of neck and back, oculomotor vision treatment, psychological treatment, and inter-disciplinary coordinated rehabilitative treatment. To be included, studies had to be intervention studies within the areas of the predefined clinical questions, include a control group, and focus on symptoms after concussion or mild traumatic brain injury (TBI). Extraction was carried out independently by multiple observers. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used for data abstraction and data quality assessment. Included studies were assessed using the Assessment of Multiple Systematic Reviews (AMSTAR) tool and the Cochrane Risk of Bias (randomized clinical trials) tool. Meta-analysis was performed for all interventions where possible. Random-effects models were used to calculate pooled estimates of effects. The level and certainty of evidence were rated; and recommendations formulated according to the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. All outcomes were planned before data collection began according to a specified protocol. The primary outcomes were the collective burden of PPCS and another outcome reflecting the focus of a particular intervention (e.g., physical functioning after graded exercise intervention). A total of 11 systematic reviews were identified but did not contribute any primary studies; 19 randomized clinical trials comprising 2,007 participants (1,064 women [53.0 %]) were separately identified and included. Evidence for the 7 interventions ranged from no evidence meeting the inclusion criteria to very low and low levels of evidence. Recommendations were weak for early information and advice, graded physical exercise, vestibular rehabilitation, manual treatment of the neck and back, psychological treatment, and inter-disciplinary coordinated rehabilitative treatment. No relevant evidence was identified for oculomotor vision treatment, so the panel provided a good clinical practice recommendation based on consensus. The authors concluded that based on very low to low certainty of evidence or based on

consensus, the guideline panel found weak scientific support for commonly applied non-pharmacological interventions to treat PPCS. Results align with recommendations in international guidelines. Intensified research into all types of intervention for PPCS is needed. Chiropractic is not mentioned as a therapeutic / management option for the treatment of PPCS.

Furthermore, an UpToDate review on “Postconcussion syndrome” (Evans, 2022) does not mention chiropractic as a management / therapeutic option.

Ultralign Adjusting Device

The SIGMA Instrument (also known as Ultralign, ProAdjuster) is a computer-based, chiropractic adjusting instrument that gently percusses the tissue area being tested, giving the practitioner vital information regarding the motion dynamics and the resonant frequency of the spinal joint or surrounding soft tissue. The SIGMA instrument measures the stiffness of the tissue or joint by applying a light mechanical force in the form of a percussion wave and oscillating frequency; a signal is then reflected back to the instrument, which then measures the spine and tissue response, sending it to the computer for interpretation, all before the muscle can respond. The process occurs so fast that it reduces the normal defense mechanism or guarding response, caused by typical palpation.

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