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On the topic:

Compliance Essentials: Initiating a Compliance Program in your Practice
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Compliance Essentials:
Initiating a Compliance Program in your Practice

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BACKGROUND

2010 – Affordable Care Act is signed into law by Pres. Obama

Section 6401 of the Affordable Care Act provides that a “provider of medical or other items or services or supplier within a particular industry sector or category” shall establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP).

The Affordable Care Act further required the Secretary of Health and Human Services (HHS), in consultation with the HHS Office of Inspector General (OIG), to establish “core elements” for provider and supplier compliance programs within a particular industry or sector. In doing so, HHS has the discretion to determine both the timeline for implementation of the core elements and the requirement to have a compliance program.

An enforcement date for provider compliance plans as mandated in the Affordable Care Act is yet to be issued. But since the late 1990s, long before the Affordable Care Act legislation mandated that providers put a compliance plan in place, the Office of Inspector General (OIG) began a major initiative to support Health care Professionals in establishing a compliance program for their offices, organizations and practices.
BACKGROUND

Affordable Care Act Compliance Program Mandate

Most health care professionals are aware that the Affordable Care Act mandates compliance programs for Medicare and Medicaid providers. Although the law speaks specifically to individual and small group practices, the intent is for all health care professionals to implement a compliance program in their offices/practices.

Although a compliance program is not a guarantee that fraud, waste, abuse or inefficiency will not occur; the OIG and CMS believe that the implementation of a good compliance program will aid in better protecting yourself from risk of improper conduct.

BACKGROUND

Benefits of a Good Compliance Program

The implementation of a compliance program should send a message that your office/practice operates in an ethical manner and is committed to quality customer/patient care, but implementing a sound compliance program can also result in numerous benefits to provider.

A well-constructed compliance program can:
- Increase the potential of proper submission and payment of claims;
- Reduce billing mistakes;
- Improve the results of reviews conducted on Medicare claims by the Medical Review Department (MR), Comprehensive Error Rate Contractor (CERT), Recovery Auditor and the Zone Program Integrity Contractor (ZPIC);
- Avoid the potential for fraud, waste and abuse; and
- Promote patient safety and ensure delivery of high quality patient care.

And as an additional note, having your own compliance program may save you valuable staff time in duplicative training. Many commercial insurance plans require providers to "attest" that they have a compliance plan and provide training to all employees as conditions of participation. If the provider does not have a compliance plan the commercial insurance will want you to complete their compliance training.
RESOURCES

• CMS offers many tools to increase your awareness of Fraud and Abuse, Medicare claims review programs as well as basic Medicare information. These tools can be found on the CMS website on the Medicare Learning Network (MLN) on the MLN products page.

• Additional information and resources are available on the MLN Provider Compliance web page at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html

What are the CORE ELEMENTS?

Seven Core Elements of an Effective Compliance Program

1. Written Policies, Procedures and Standards of Conduct
2. Compliance Program Oversight
3. Training and Education
4. Corrective Actions
5. Auditing and Monitoring
6. Consistent Discipline
7. Opening the Lines of Communication
The Seven Elements of a Compliance Program

- A brief description of the seven essential elements of an effective Compliance Program as suggested by the OIG is:
  1. Implementing Written Policies
  2. Designating a Compliance Officer/Contact
  3. Conducting Comprehensive Training and Education
  4. Developing Accessible Lines of Communication
  5. Conducting Internal Monitoring and Auditing
  6. Enforcing Standards through well publicized disciplinary guidelines
  7. Responding Promptly to detected offenses and undertaking corrective action

Source: Federal Register / Vol. 64, No. 192 / Tuesday, October 5, 1999 / Notices

As you can see by the date of initiation from the Federal Register, this has been in place for 17 years. The difference is that now ACA MANDATES Compliance. Prior to 2010 this was voluntary.

Checklist

✓ Can I name the seven elements of an effective Ethics and Compliance program?
✓ Does everyone in my organization understand what the seven elements of Compliance are?
Element #1 - Written Policies and Procedures

- What MAIN TOPICS of policies and procedures should be covered/identified?
  - Compliance Program Overview (Mission Statement)
  - Compliance Program Structure (Assignment, duties of compliance office, chain of command, methods for reporting non-compliance, non-retaliation policies, etc.)
  - Coding-Billing-Reimbursement (Policies for ethical coding, insurance billing EOB review, auditing, etc.)
  - Education and Training (Degree and certification requirements of employees, annual training and continuing ed requirements, etc.)
  - Laws, Statutes, Regulations and Guidelines (HIPAA, OSHA, FMLA, ADA, Anti-Kickback, Stark, etc.)
  - Operating Policies (Office Hours, floor plan, handling medical emergencies in the office, patient billing and collection policies, patient check-in/check out policy, pl. registration/preregistration, insurance verifications, professional courtesy policy, medical records standards and records retention policies, quality assurance, etc.)
  - Pharmaceuticals/Biologicals – (Inventory Management, security of pharmaceutical samples, expiration dates, drug disposal procedures)
  - Laboratory – (Laboratory billing practices, CLIA certification, referrals, specimen collection procedures, etc.)
  - Radiology and Ancillary Testing (List of radiology and ancillary procedures performed in office, i.e.: EKG, Ultrasound, Pulmonary Function, vision testing, etc. Referral policies, certification, training and continuing ed. requirements of personnel, names of personnel authorized to perform radiology/diagnostic services and credentials)
  - Civil Rights (Use/access to translators, communication with sensory impaired patients, Title VI compliance of the Civil Rights Act of 1964 i.e.: non discrimination policy; age discrimination, disability discrimination, grievance policy, etc.)
  - Personnel Policies (EOE policies, personnel organizational chart, definitions of part time/full time. Policy for overtime hours, vacation, personal leave, jury duty, funeral leave, paid holidays, etc. Certification requirements, OME’s and fiscal responsibility, signature verification form, disciplinary policy, maintenance of employee records, promotion/transfer policy, conditional employment policy, employee evaluations, pay structure and raises. Inclement weather policy, procedure/policy for calling in sick, dress code, hygiene code, smoking policy, substance abuse policy, breaks, cell phone policy, personal computer use during office hours, social media policy, clinic security policy, employee grievance policy, harassment policy)
  - Job Descriptions – Every position in the clinic should have a detailed job description. Include requirements for education, certifications, etc. This includes job descriptions for the Medical Director, Practice Manager, PR Director, HR Director, Compliance Officer, Physicians, Clinicians, Office Personnel, Janitorial staff, etc.
  - Mission Statement

Mission Statement

- All compliance programs should begin with a Mission Statement, aka Code of Conduct

Western Medical Associates is committed to providing quality, comprehensive healthcare to the patients of our community. Our services will be provided in a professional manner within a safe and orderly environment. All personnel will be expected to maintain high moral and ethical standards, and abide by State and Federal regulations as they pertain to the delivery of health care. All personnel will adhere to the office compliance policies. In order to maintain our highest intent of compliance integrity, if you have any knowledge or suspect any type of fraud or abuse, you are to bring it to the attention of the compliance officer. You may also report incidences, if not resolved within the practice, directly to the Federal Government at:

PHONE: 1-800-HHS-TIPS (1-800-447-8477)
Email: https://tips.os.dhhs.gov
Mail: Office of Inspector General, DHHS, ATTN: HOTLINE, 330 Independence Ave, SW.
Washington, DC 20201

Questions or concerns should be brought to the attention of the compliance officer.

Signature of Clinic Owner ____________________________
Date _________________
Where to start?

• You can build your own from scratch, using the guidelines from the Federal Register/Vol. 65, No. 194/ Thursday, October 5, 2000/Notices, and other reference material found at the OIG website.

• You can get templates for a Compliance Manual from an organization such as the Healthcare Compliance Association (HCCA)
  – http://www.hcca-info.org/Products.aspx

• You can have a Compliance Manual custom made by a reputable Compliance Consulting firm/company

• Compliance info for Medical Board of Directors

• Remember, Compliance Manuals are not a “plug and play” product. They must be customized to your practice and reviewed annually for updates.

Checklist

✓ Based on the topics from the previous slides, do I/we have a comprehensive written policies and procedures manual?

✓ Have we developed a Mission/Code of Ethics Statement?
Developing your Manual

• Master Manual for Entire Clinic
• Departmental/Specialty Manual for each area of the practice, if applicable (Multispecialty)
• Look at what you have, and build around it. If you already have a comprehensive HIPAA and OSHA manual, this will simply integrate in to the Compliance Manual. Make sure all content is current and reflects the most recent regulations.

Checklist

✓ Do I/we have a certain components of a Compliance Manual that we can build on?
✓ Have those portions of the manual been reviewed lately and updated with the most current and relevant regulatory information?
Element #2 – Your Compliance Officer

- Monitor/Oversight of Compliance program
- Coordinates ongoing training
- Forms compliance team – delegates different areas of compliance. Example, nurse might be the OSHA POC, Billing manager the Billing and coding compliance POC, etc..
- Updates to manual
- Handles complaints
- Reports non-compliance to Physician, Practice Manager, Board of Directors
- First responder in the event of on-site Audit/Investigation (FBI, Medicare, etc.)
- Can be a person or company independent of the clinic. But they must be willing to take on the role of a compliance OFFICER, not just a compliance consultant

Checklist

✓ Do I/we have a compliance officer?
✓ Have we developed a compliance team to work with the Compliance officer on implementation of the compliance program?
Element #3 Training and Education

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:
1. Determining who needs training (both in coding and billing and in compliance);
2. Determining the type of training that best suits the practice’s needs (e.g., seminars, in-service training, self-study or other programs); and
3. 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, 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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices
Element #3 Training and Education

Conducting Appropriate Training and Education

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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

Format of the Training Program
Training may be conducted either in-house or by an outside source. 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.

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. 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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices
Checklist

✓ Has everyone in the organization received Compliance training in the past 12 months?
✓ Has the billing department received additional training on coding and billing compliance?
✓ Do we have a training program schedule for the next 12 months?

Element #4 – Open and Accessible Lines of Communication

• Establish a clear chain of command
• Establish OPEN DOOR policy
• Establish Non-Retaliation policy
• Allow for anonymous reporting
  – Create email account ex: compliance.concerns@westernclinics.com
  – Grievance box
  – Advise staff that you will do everything you can to keep report anonymous, but sometimes that may not be possible
• Give employee contact info for DHHS
  PHONE: 1-800-HHS-TIPS (1-800-447-8477)
  Email: https@os.dhhs.gov
Element #4 – Open and Accessible Lines of Communication

• Main reason employee will not report violations to Compliance Officer or Supervisor is fear of retaliation
• Main reason for Qui-Tam (Whistleblower) suits against a practice/physician

Checklist

✔ Does everyone in the organization know who the compliance officer is?
✔ Does everyone know the Chain Of Command for reporting compliance violations?
✔ Does everyone know the various methods they can use for reporting violations?
✔ Do we have an effective Open Door Policy?
✔ Do our employees feel confident in our non retaliation policy?
Element #5 Internal Monitoring and Auditing

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

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

Element #5 Internal Monitoring and Auditing

Standards and Procedures Audit

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–10–CM codes).

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices
Element #5 Internal Monitoring and Auditing

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. 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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

The Baseline Audit

• 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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices
The Baseline Audit

- 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. 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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

The Baseline Audit

- 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.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices
Checklist

- Have we conducted a Policies and Procedures review of our Compliance Manual in the past 12 months?
- Have we conducted a Baseline audit of our billing practices?
- Are we performing our audits concurrent with billing or retrospectively?
- Are we auditing at least 5 claims/per provider/per federal payer/per year?

Element #6 – Consistent Discipline

*Enforcing Disciplinary Standards Through Well-Publicized Guidelines*

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.

Source: *Federal Register* / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices
Element #6 – Consistent Discipline

- 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 disciplinary action.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

Checklist

- Do I/we have written policies to enforce consistent disciplinary steps in the event of a compliance infraction?
- Are those policies reviewed with every new employee, and with all employees annually?
- When infractions occur, do we follow through with the disciplinary guidelines, thereby enforcing and legitimizing them?
Element #7- Corrective Actions

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.

• As appropriate, such steps may involve a corrective action plan, the return of any overpayments, a report to the Government, and/or a referral to law enforcement authorities.

Source: Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

Checklist

✓ For each policy and procedure in our compliance manual, do I/we have a written policy for corrective action.

✓ When appropriate, do we follow through with corrective action steps and document those actions in our Compliance Manual?
FINALLY....

• An EIGHTH core element is being added to your compliance program

All employees of your organization should be checked on the OIG Exclusion Database on a MONTHLY basis to make sure they are not an excluded individual or entity. If they are on the exclusion list, this means they are excluded from the Medicare program and cannot see/treat or receive any financial gain from a Medicare patient or any other federally funded program.

https://exclusions.oig.hhs.gov/

Questions?

• Thank you for your attendance!

• Get your questions answered on PMI’s Discussion Forum: http://www.pmimd.com/pmiForums/rules.asp

• Email Lisa Maciejewski-West at lmaciejewski@pmimd.com