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Medicare Accountable Care Organizations

An overview of shared savings program compliance requirements

INTRODUCTION

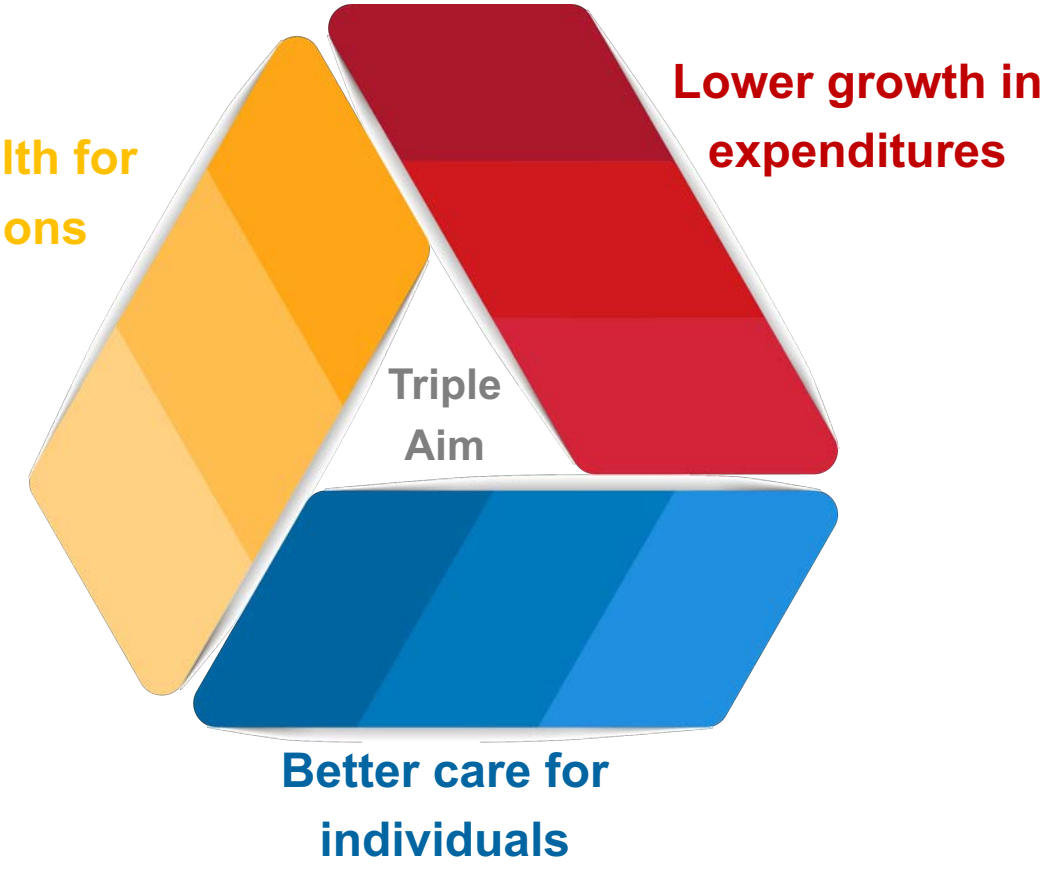
Methodist & Nebraska Medicine formed the Nebraska Health Network as an Accountable Care Organization (ACO) that participates in the Medicare Shared Savings Program (MSSP) and other value-based agreements.

- For MSSP, each ACO signs an agreement with the Centers for Medicare & Medicaid Services, which requires that the ACO and all individuals and entities providing services to the ACO, meet the requirements of the program.

- Although this training may seem similar to a compliance program you've completed through your organization, this program is separate and unique to the ACO and ACO activities (e.g. care coordination, quality reporting and cost saving initiatives.)

HISTORY IN THE MAKING

The Centers for Medicare & Medicaid Services (CMS) established the Medicare Shared Savings Program (MSSP) as part of the Affordable Care Act (ACA) to improve the quality of health care delivered to Medicare Fee-For-Services beneficiaries (Beneficiaries) and reduce unnecessary costs.



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WHAT IS (and is not) AN ACO?

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ACOs are not

- Medicare Advantage Plans
- HMO

The Shared Saving Program financially rewards ACOs that lower growth in health-care costs while meeting performance standards on quality of care.

HOW AN ACO IMPACTS THE BENEFICIARY

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1. Beneficiaries are not members of the ACO and do not enroll in the ACO.

2. They may continue to see any provider who accepts Medicare regardless of participation in an ACO; there is no limit or restriction on provider choice.

3. Their benefits are unchanged – they retain the same Medicare coverage, including Medicare Supplement plans.

HOW AN ACO IMPACTS THE BENEFICIARY

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4 Beneficiaries still have access to Medicare customer service, and Medicare continues to remit claims payments on behalf of Beneficiaries.

5 Beneficiaries cannot opt-out of the ACO. They can elect to prohibit CMS from sharing their claims data with the ACO, but this only prohibits data sharing.

HOW AN ACO IMPACTS THE BENEFICIARY

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The Beneficiary will still be assigned to the ACO and the ACO is still responsible for the overall cost and quality of the Beneficiary's care.

The Beneficiary can opt-out of and, conversely, opt back into data sharing at any time.

IMPROVED CARE FOR BENEFICIARIES

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Nebraska Health Network Beneficiaries should experience an improvement in care coordination as a result of their provider's participation in the ACO.

IMPROVED CARE FOR BENEFICIARIES

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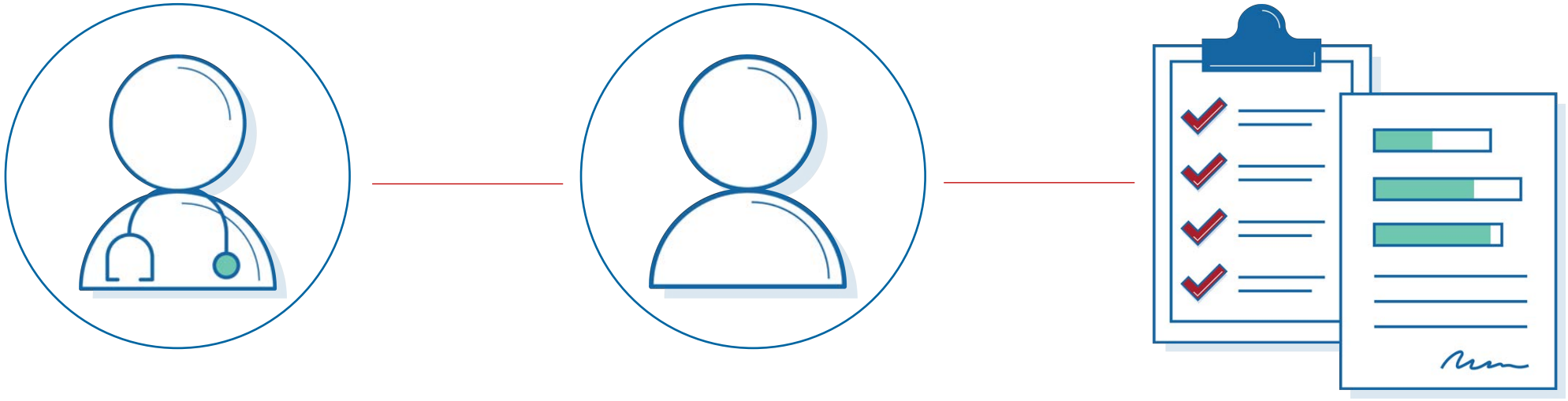

They will be encouraged to visit their primary care provider and discuss care plans.

IMPROVED CARE FOR BENEFICIARIES

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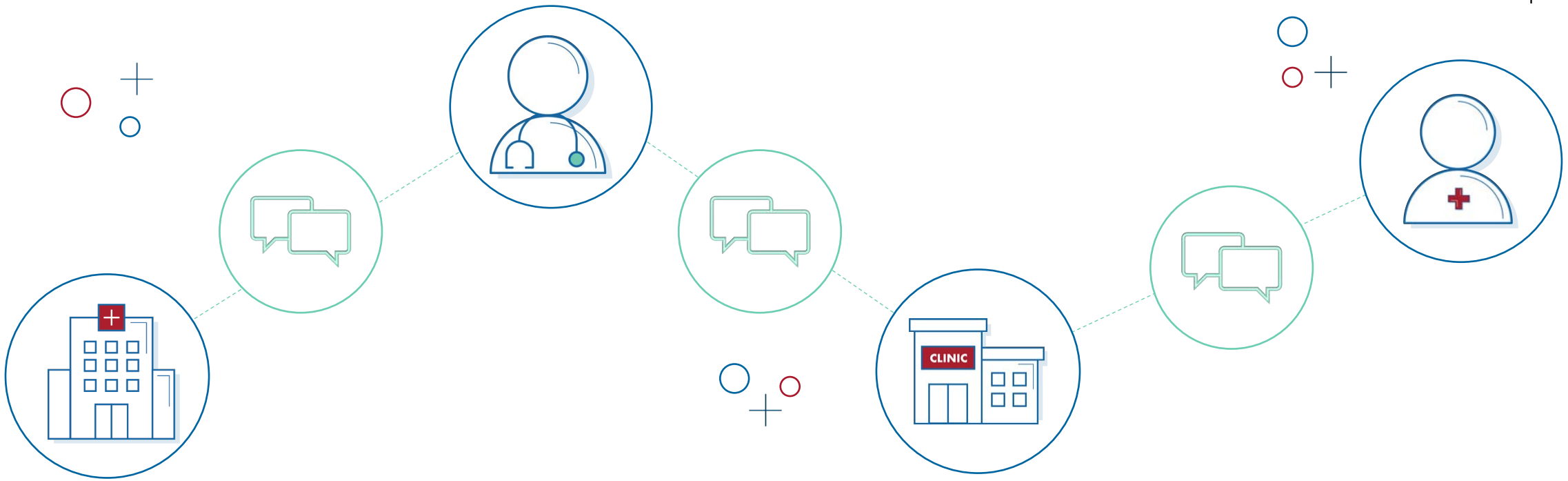

Their health-care team will communicate with each other.

IMPROVED CARE FOR BENEFICIARIES

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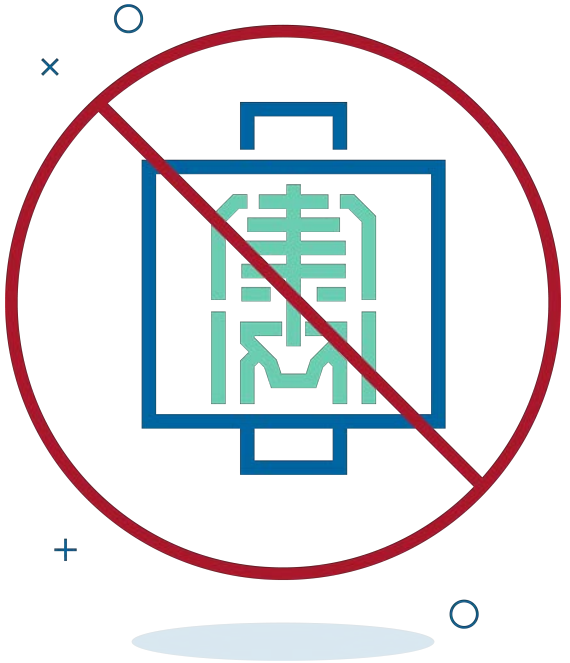

They will avoid duplicative medical tests and forms because results can be shared among the health-care team.

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HOW YOU CAN SUPPORT THE ACO

SUPPORT THE ACO BY:

- Completing the annual ACO training (e.g. Annual Compliance Training)
- Educating beneficiaries about the ACO
- Coordinating care with other providers as appropriate
- Conducting complete and accurate quality reporting
- Participating in the leadership and governance of the Nebraska Health Network, as appropriate

COMPLIANCE PROGRAM REQUIREMENTS

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ACOs are required to have a Compliance Program. Under the MSSP, the Compliance Program must contain the following 5 elements:

Compliance Officer

Mechanisms for Identifying Issues

Compliance Training

Method for Anonymous Reporting

Requirement for Reporting Violations of Law

At any time, CMS may audit our ACO to verify compliance with these requirements.

Compliance Officer

Each ACO has a Compliance Officer who is responsible for the implementation and oversight of the ACO's Compliance Program. The Compliance Officer is **NOT** the ACO's legal counsel. You can contact the ACO Compliance Officer with any questions or concerns about the ACO.

msspcompliance@nebraskahealthnetwork.com

CONTACT COMPLIANCE OFFICER

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- ❑ If you have **questions** about ACO policies and procedures
- ❑ When you are starting to implement **new initiatives** and have **ideas** related to the ACO
- ❑ You have **concerns** over actions of an entity or individual providing services related to ACO activities

Appropriate contact allows the Compliance Officer to report to ACO officials to comply with the Compliance Plan requirements.

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MECHANISMS FOR IDENTIFYING ISSUES

PREVENTION

The ACO has adopted Policies & Procedures (P&Ps) to help ensure that regulatory requirements are met. The P&Ps are the basic plan to prevent compliance issues from occurring.

DETECTION

The Compliance Officer oversees the ongoing and comprehensive Monitoring & Oversight program to ensure the ACO is meeting the standards set forth in the policies and procedures, as well as additional program requirements.

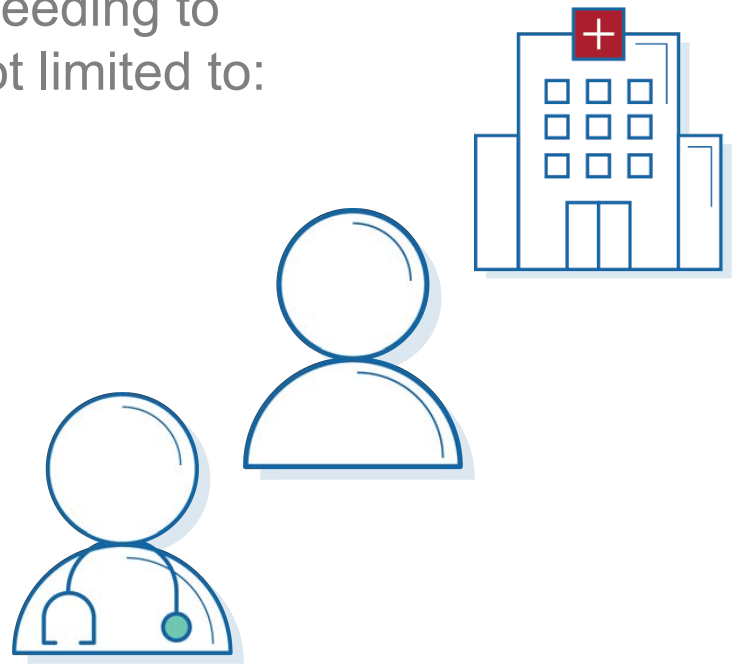
CORRECTION

Once issues are identified, the ACO Compliance Officer works with the appropriate business areas to correct the issue. Correction may be done through the implementation of an Internal Corrected Action Plan (iCAP) and/or disciplinary action.

EFFECTIVE TRAINING PROGRAMS

The ACO is required to implement an effective compliance training program for the ACO, ACO Participants and ACO Provider/Suppliers. Individuals needing to complete ACO-related compliance training may include, but are not limited to:

- Members of the ACO's Board of Directors and Sub-Committees
- ACO participants, providers, suppliers and staff



The training program includes, but is not limited to, the following topics:

- What constitutes program violations
- How to recognize violations

ANONYMOUS REPORTING

The ACO has implemented an online system that allows an individual to anonymously report compliance concerns. You can use this link to report compliance concerns 24 hours a day, 7 days a week.

NebraskaHealthNetwork.com/compliance/

Anyone can report at any time! Each person working with the ACO has a duty to report any compliance concerns.

The ACO has a Non-Retaliation Policy for anyone making a report in good faith. As long as you are not intentionally making a false claim, nothing bad can happen to you for contacting compliance. There is zero tolerance for **any** retaliatory action.

If you ever believe that you are being retaliated against for any reason, you should contact the ACO Compliance Officer.

REPORTING PROBABLE VIOLATIONS OF LAW

ACOs must report probable violations of law to an appropriate law enforcement agency. The ACO Compliance Officer works with legal counsel and the ACO's Board of Directors to determine whether a report should be made.

REPORTING PROBABLE VIOLATIONS OF LAW

You are responsible for reporting any compliance concerns through one of the following methods:

Compliance Officer

You can hand-deliver or mail information to:

ACO Compliance Officer
9140 W. Dodge Road, Suite 400
Omaha NE, 68114

Website

Submit your concern on the NHN Compliance Website:

NebraskaHealthNetwork.com/compliance/

Supervisor

Express your concerns to your supervisor

PRIVACY CONCERNS - HIPAA

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- The Health Insurance Portability and Accountability Act (“HIPAA”) applies to the ACO and its providers/suppliers. HIPAA and its regulations establish national standards for the protection of individually identifiable health information.
- The ACO and providers/suppliers are required to implement certain physical, administrative and technical safeguards intended to protect the privacy and security of patients’ health information.
- The ACO must make reasonable efforts to use and disclose only the minimum amount of PHI necessary. Inappropriate access, use or disclosure of patient health information must be immediately reported in order to properly notify affected individuals.

PRIVACY CONCERNS – ACO REQUIREMENTS

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- ACOs must meet additional privacy requirements above the standard HIPAA privacy rules.
- CMS no longer requires ACOs to submit addenda to make changes to their Data Use Agreements (DUA). All ACO contacts listed in ACO-MS will be considered DUA Custodians. These individuals are responsible for the observance of all conditions of data use and for establishment and maintenance of security arrangements as specified in the DUA to prevent unauthorized use or disclosure. DUA Custodians can access the requested data files and must oversee others within the organization who have access to the files.
- ACOs are responsible for tracking their own subcontractors and noting the date the ACO started and/or stopped sharing data with the subcontractor and confirmation that any subcontractor they no longer work with has destroyed any data given to them by the ACO.

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PRIVACY CONCERNS: INFORMATION BLOCKING

RULE

Health-care providers are **prohibited from engaging** in any act or omission that is likely to interfere, prevent or materially discourage the **access, exchange or use of electronic health information** unless an exception applies.

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APPLICATION

ACO participants and providers/suppliers should be **aware of these rules** and **pay attention to developments** related to federal blocking regulations and enforcement activities. **Providers and suppliers should consult their legal counsel and compliance officers** regarding appropriate steps to take when providing access, exchange or use of electronic health information and document the processes accordingly.

SURPRISE BILLING

- Surprise billing occurs when an individual chooses an **in-network provider** or facility and unknowingly has an **out-of-network provider** involved in his/her care.

- The **No Surprises Act** became effective Jan. 1, 2022. This Act has three general components: (1) a prohibition on surprise billing; (2) protections for uninsured or self-pay individuals; and (3) disclosure requirements.

SURPRISE BILLING PROHIBITION

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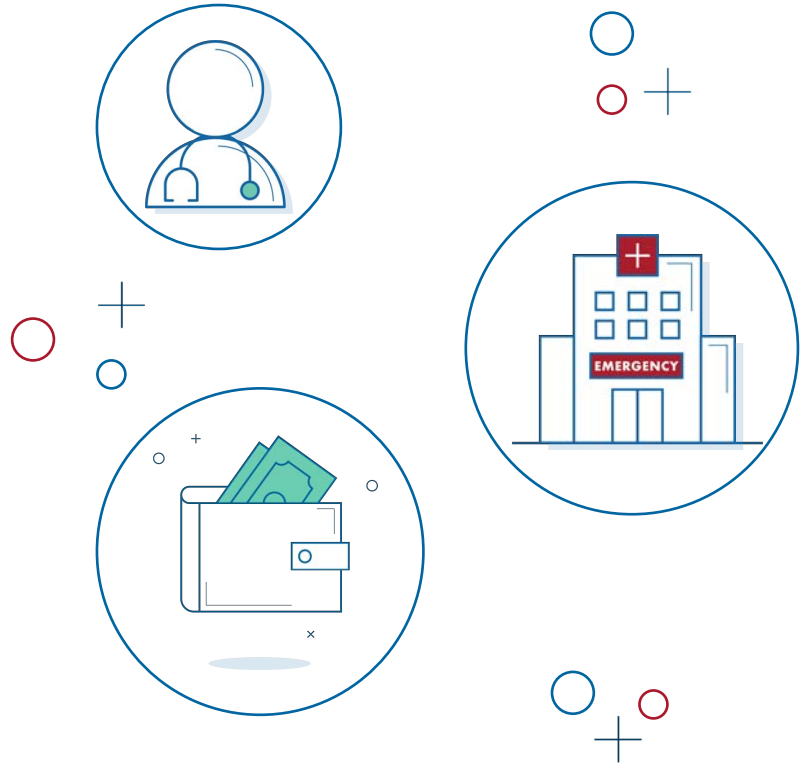
- **Out-of-network facilities and providers** must not bill for **emergency service** payment amounts that exceed an individual's cost sharing requirements.
- **Out-of-network providers at in-network facilities** performing **non-emergency services** must not bill for items or services furnished that exceed an individual's cost sharing requirements.
- Exceptions apply to each of those.



PROTECTIONS

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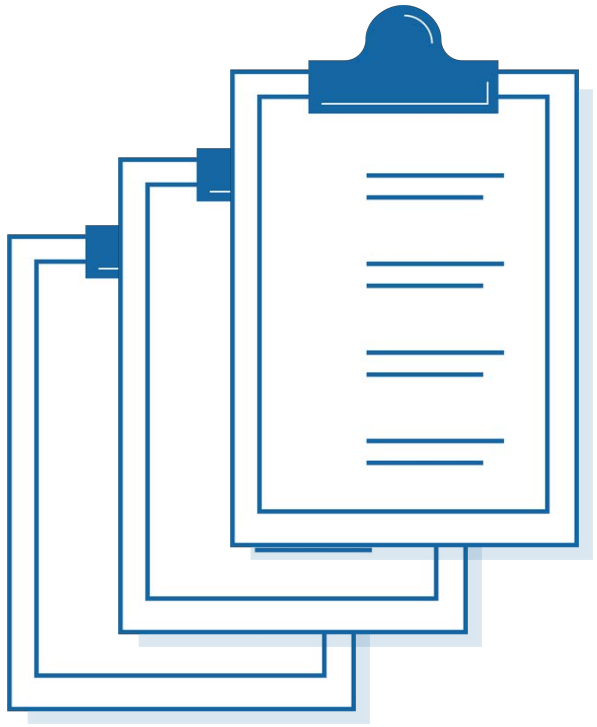
- “Good faith estimate” forms must be delivered orally and in writing to uninsured and self-pay individuals.

- Such estimates may be challenged by these individuals if the actual cost of the care exceeds the estimate by **$400.**

DISCLOSURE REQUIREMENTS

- Providers and facilities must publish certain model notice forms available from CMS.
- These forms contain information about the No Surprises Act requirements, how state law applies and who to contact if the patient believes that the Act is being violated.



MARKETING COMPLIANCE

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ACOs are required to submit all “marketing materials” to CMS for approval prior to use. If any changes are made to an approved material, it must be resubmitted.

- The ACO must wait for the “File & Use” period to lapse prior to utilizing materials filed with CMS, unless CMS grants approval prior to the end of the File & Use period.
  - The “File & Use” period is five days for the MSSP.
  - CMS can disapprove a material after the close of this period. If this occurs, the ACO must immediately stop using the material and correct identified issues.

Marketing Materials are defined in the regulations as any general audience material used to educate, solicit, notify or contact Beneficiaries or provider/suppliers regarding the program.

RED FLAG COMPLIANCE ISSUES FOR ACOs

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CHERRY PICKING

The ACO should avoid programs or activities that encourage healthy/low-cost Beneficiaries to remain in, or receive services from, the ACO or discourage high risk/cost Beneficiaries from utilizing the ACO. This can happen intentionally or be an unintended result of a program or activity.

- Be sure to review for appearance of impropriety.
- Document intent of any new program clearly.
- Always work with Compliance to implement any new programs or initiatives. This will allow for a risk analysis and review of any potential prior to implementation.

RED FLAG COMPLIANCE ISSUES FOR ACOs

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MANAGED CARE/NETWORKS

Avoid any language or activity suggesting that Beneficiaries must receive services from the ACO or any ACO Participant or Provider/Supplier. Beneficiaries retain freedom of choice, even if their provider is participating in an ACO.

MEDICAL LIABILITY

Avoid language creating the appearance of a physician/patient relationship between the Beneficiary and the ACO. The ACO does not provide care and suggesting otherwise can create unnecessary risk and liability for the ACO.

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FRAUD, WASTE AND ABUSE LAWS

FRAUD, WASTE AND ABUSE LAWS

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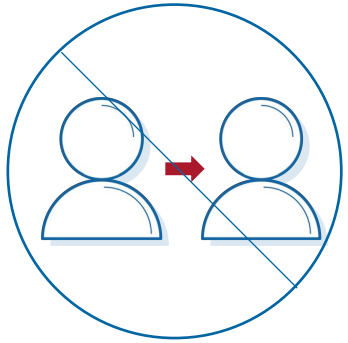
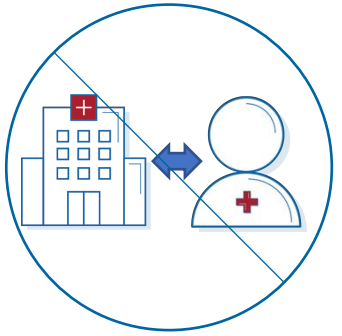
There are five federal fraud, waste & abuse laws that all ACOs must understand and avoid:

Stark Law (Physician Self-Referral)



Anti-Kickback Statute

False Claims Act (FCA)



Gainsharing Civil Monetary Penalty (CMP)

Beneficiary Inducement CMP

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DEFINING FRAUD

Fraud is generally defined, in any jurisdiction, as a material misrepresentation of a fact that someone relies on to their detriment.

For our purposes, this generally means that a Beneficiary or CMS relies upon some action of an ACO or provider, and pays an inaccurate claim or receives an inappropriate service as a result.

STARK LAW (PHYSICIAN SELF-REFERRAL)

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- This law prohibits a physician from **making referrals for certain designated health services** to an entity in which the physician (or an immediate family member) has an **ownership/investment interest or with which he or she has a compensation arrangement**, unless an exception applies.
- Stark Law also prohibits health-care providers from presenting a claim or bill for these services – or to cause a claim or bill to be presented.
- A physician generally makes a referral if he or she requests or orders an item or service covered by Medicare.
- Stark Law is a strict liability statute, meaning proof of intent to violate the law is not required.

VIOLATIONS OF STARK LAW

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EXAMPLE

MSSP BENEFICIARY

- Patient needs blood work
- Physician has partial ownership interest in the lab

A physician refers a beneficiary to complete blood work with a lab in which the physician has partial ownership interest.

VIOLATIONS OF STARK LAW

Penalties for violating Stark Law may include fines up to $15,000 per service, an assessment of up to three times the amount paid, as well as exclusion from participation in all Federal health-care programs.

Any physician or entity that knowingly participates in a scheme to circumvent the Stark Law is subject to a CMP of up to $100,000 and may be excluded from participation in Federal health-care programs.

ANTI-KICKBACK STATUTE

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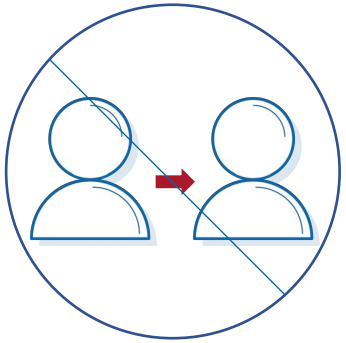
The Anti-Kickback Statute (AKS) makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services that are reimbursable by a Federal health care program, such as Medicare.

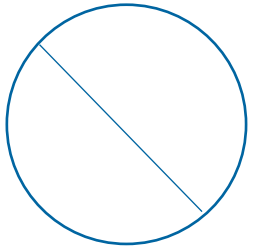


Simply put, AKS prohibits **knowingly and willfully** exchanging remuneration for the referral of patients for items or services covered by a Federal health care program.

EXAMPLE

A hospital pays a provider each time the provider refers a Medicare Beneficiary to the hospital.

FEDERAL FALSE CLAIMS ACT



The Federal False Claims Act (FCA) protects the Federal Government from being overcharged or sold substandard goods or services.

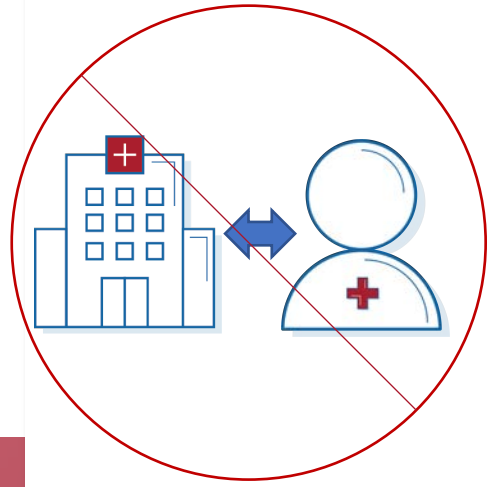
FCA imposes civil liability on any person who **knowingly** submits or causes a false or fraudulent claim to be submitted to the Federal Government.

Violations of the Stark Law or Anti-Kickback Statute can create liability under the FCA.

EXAMPLE

Up-coding Services: Up-coding occurs when a provider submits a claim representing a more serious/expensive procedure than was actually performed

GAINSHARING CIVIL MONETARY PENALTY



The gainsharing Civil Monetary Penalty (CMP) prohibits hospitals from making payments to physicians to encourage reductions or limitations on services.

EXAMPLE

Hospitals may not increase a physician's salary as a reward for reduction in the number of procedures completed.

BENEFICIARY INDUCEMENT CMP

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The gainsharing Civil Monetary Penalty (CMP) prohibits hospitals from making payments to physicians to encourage reductions or limitations on services.

EXAMPLE | A physician provides gift cards for Beneficiaries who complete the Annual Wellness Visit.

NOMINAL VALUE EXCEPTION

Incentives may be provided as long as each of the following are met:

- The incentive is not cash or a cash equivalent
- The incentive is valued at less than $15 in each instance
- No individual receives more than $75 in incentives annually

MEDICARE FWA WAIVERS

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Shared Savings Program and Next Generation ACOs are allowed to utilize four waivers of the fraud, waste and abuse laws. The 4 waivers available to currently participating ACOs are:

- ACO Participation Waiver
- Shared Savings Distribution Waiver
- Compliance with Physician Self-Referral (Stark) Law Waiver
- Patient Incentives Waiver

NONE OF THESE waivers apply to state laws!

MEDICARE FWA WAIVERS

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ACOs can use these waivers in creative ways to help meet the Program's purposes of:

- Promoting accountability for quality, cost and overall care of Medicare Beneficiaries;
- Managing and Coordinating Care; and
- Encouraging investment in infrastructure and redesigned care processes.

ACO Participation Waiver

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The ACO Participation Waiver allows the ACO to waive Stark Law, Federal Anti-Kickback Statute and the Gainsharing CMP. This waiver applies broadly to ACO-related arrangements during the term of the ACO's participation agreement, so long as the following are met:

PARTICIPATION

RELATION TO PURPOSES OF THE PROGRAM

GOVERNANCE

DOCUMENTATION

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PARTICIPATION

The ACO has entered into a Participation Agreement with CMS and remains in good standing.

GOVERNANCE

The ACO meets governance, leadership and management requirements.

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RELATION TO PURPOSES OF THE PROGRAM

ACO Board of Directors have determined that the arrangement is reasonably related to the purposes of the Program.

DOCUMENTATION

The ACO meets certain documentation and public disclosure requirements.

SHARED SAVINGS DISTRIBUTION WAIVER

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The Shared Savings Distribution Waiver protects the ACO from Stark Law, Federal Anti-Kickback Statute and the Gainsharing CMP. This waiver applies to distributions and uses of shared savings payments earned under the Program, so long as all requirements are met.

The ACO has entered into a Participation Agreement with CMS and remains in good standing.

Shared Savings are earned by the ACO during the term of the Participation Agreement, even if the actual distribution or use of the Shared Savings occurs after the Participation Agreement expires.

The Shared Savings are distributed to ACO providers or used for activities that are reasonably related to the purposes of the Program.

The Shared Savings are earned by the ACO pursuant to the MSSP.

COMPLIANCE WITH STARK LAW WAIVER

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The ACO can waive the Federal Anti-Kickback Statute and the Gainsharing CMP for ACO arrangements that implicate the Stark Law and meet an existing Stark Law Exception, so long as the following are met:

PARTICIPATION

The ACO has entered into a Participation Agreement with CMS and remains in good standing.

COMPLIANCE WITH STARK LAW

The relationship fully complies with one of the existing exceptions to Stark Law. Exceptions are listed at 42 CFR 411.355 through 411.357.

RELATION TO PURPOSES OF THE PROGRAM

The financial relationship involved is reasonably related to the purposes of the Program.

PATIENT INCENTIVES WAIVER

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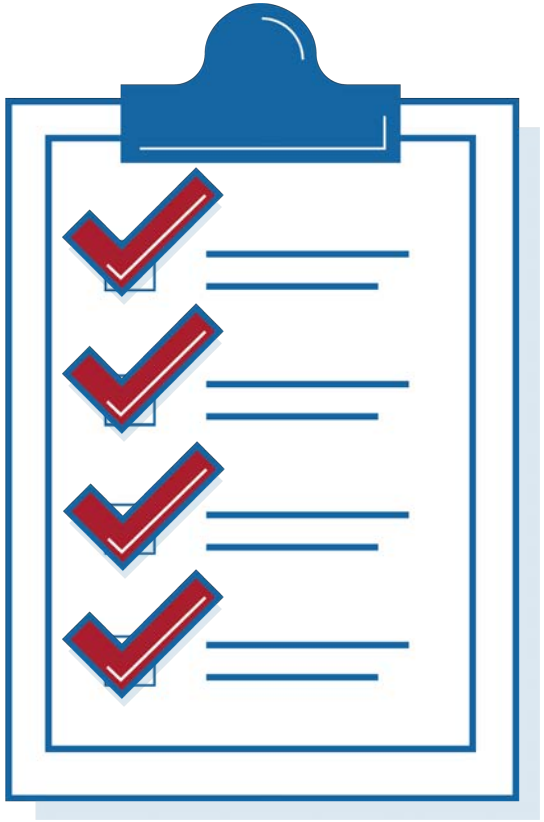
This allows ACOs to waive the Beneficiary Inducements CMP and the Federal Anti-Kickback Statute for medically-related incentives offered by ACOs.

Waiver prohibits the use of inducements as an incentive for the Beneficiary to receive services from, or remain in, the ACO.



Incentives cannot be cash or cash equivalents and must be offered to encourage preventive care and compliance with treatment regimes.

PATIENT INCENTIVES WAIVER

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While ACOs are still prohibited from using inducements as an incentive for the beneficiary to receive services from, or remain in, the ACO – this waiver does allow the ACO to provide incentives to encourage preventive care and compliance with treatment regimens so long as certain requirements are met.

KEY REQUIREMENTS

- There must be a reasonable connection between the item/services provided and the medical care of the beneficiary.
- The item/services are in-kind (no cash or cash equivalents)
- The items/services advance one of the following clinical goals:

  - Preventive care
  - Adherence to a treatment or drug regime
  - Adherence to a follow-up care plan
  - Management of a chronic disease or condition

If you have an idea for how to utilize one of the waivers, contact the ACO Compliance Officer to ensure that:

- Use of the waiver has been appropriately documented for audit purposes
- All requirements are met
- All necessary approvals are obtained

REPORT YOUR CONCERNS!

If your have a concern related to ACO activities or initiatives, you have a duty to report.

You can report at any time using one of these three options:

Compliance Officer

Contact the ACO Compliance Officer:

mssp@nebraskahealthnetwork.com

Website

Submit your concern on the NHN Compliance Website:

NebraskaHealthNetwork.com/compliance/

Supervisor

Express your concerns to your supervisor

ONLINE ATTESTATION

Please complete the online attestation to notify NHN that you completed the Compliance Training.

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