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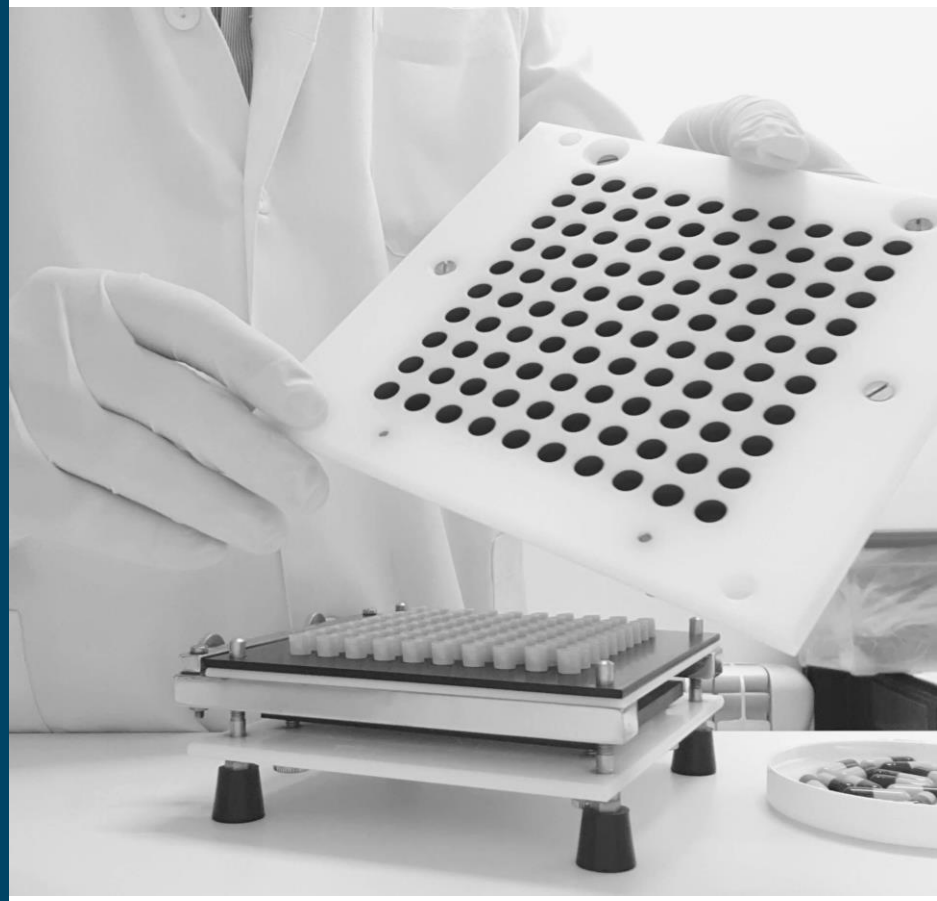
Building Strong Relationships with Referral Sources

Denise M. Leard

September 25, 2024



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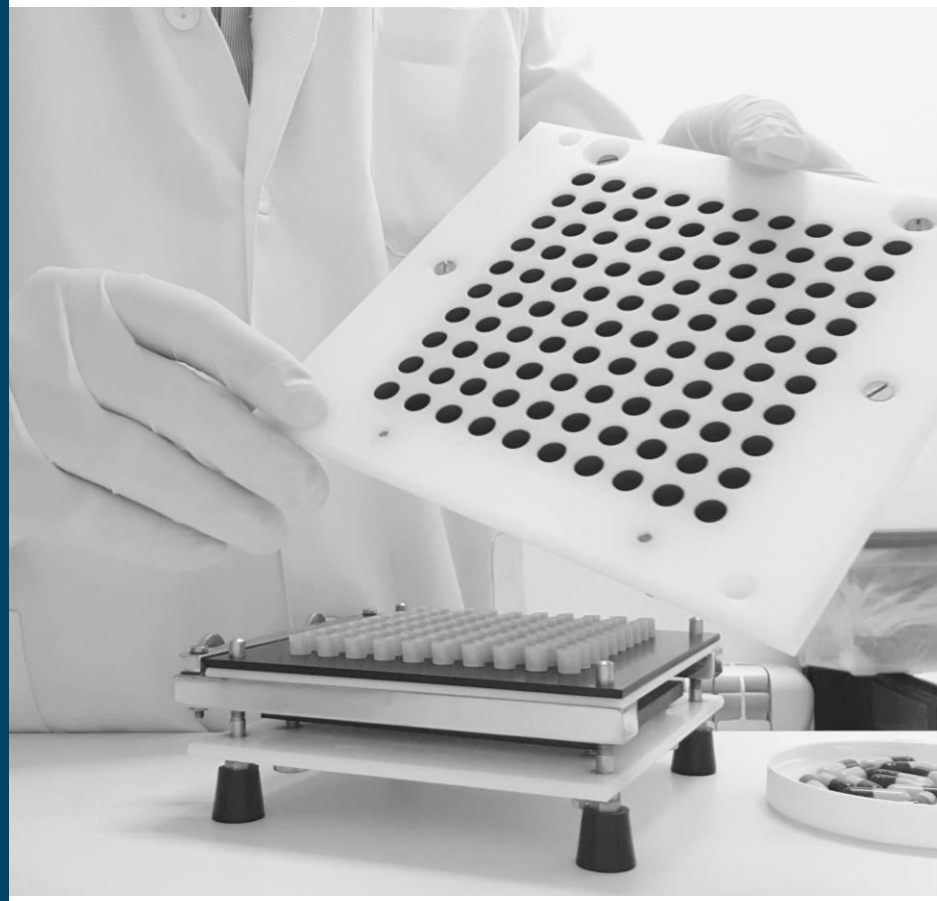
Introduction



Introduction

- The “Greatest Generation” consisted of 23 million Americans.
- We now have 78 million “Baby Boomers” … those born between 1946 and 1964.
- Boomers are retiring at the rate of 10,000 per day.
- The life span of Boomers is greater than earlier generations.
- As Boomers age, the demand for health care will increase exponentially.
- At the same time, there is a limited amount of money to pay for this health care.

Introduction

- This is the proverbial “irresistible force” meeting the “immovable object.”
- In order to succeed in today’s hyper-competitive environment, pharmacies, home health agencies, hospices, DME suppliers, and similar providers (collectively referred to as “providers”), must establish their niche. They must “think outside the box.”
- The successful provider must set itself apart from its competition.
- One very important way to do this is for the provider to enter into relationships with physicians, hospitals, pharmacies, long term care facilities, and other referral sources.
- In doing so, it is critical that the provider comply with federal and state anti-fraud laws.

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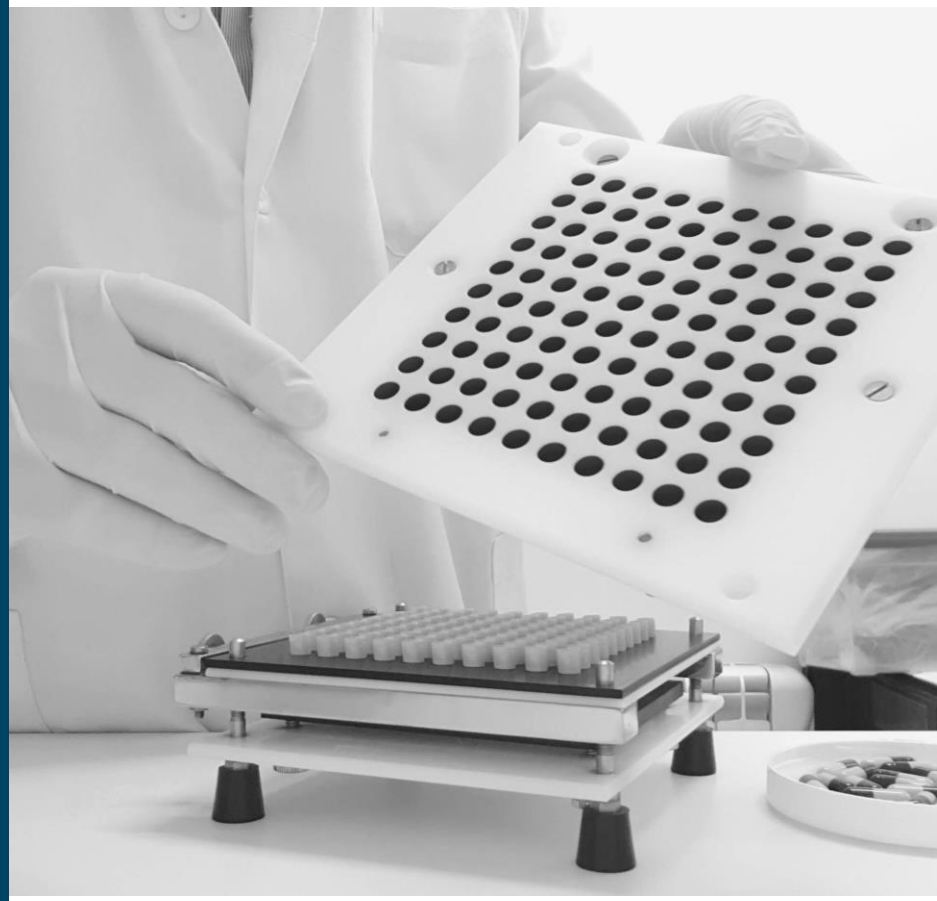
Legal Guidelines



Federal Anti-kickback Statute

- It is a felony for a health care provider to knowingly and willfully offer or pay any remuneration to induce a person/entity to refer an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.

Federal Beneficiary Inducement Statute

- This statute prohibits a provider from offering or giving anything of value to a Medicare beneficiary that the provider knows, or should know, is likely to persuade the person to purchase an item covered by a federal health care program.
- In the preamble to the regulations implementing this statute, the OIG stated that the inducement statute does not prohibit the giving of incentives that are of "nominal value."
- The OIG defines "nominal value" as no more than $15 per item or $75 in the aggregate to any one beneficiary on an annual basis.
- "Nominal value" is based on the retail purchase price of the item.

Federal Physician Self-Referral Statute ("stark")

- This statute provides that if a physician has a financial relationship with an entity providing "designated health services," then the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.
- Designated health services include home health; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; out-patient prescription drugs; and rehab therapy services.
- One of the exceptions to Stark provides that a provider may provide non-cash equivalent items to a physician if such items do not exceed an annual amount established by CMS. For 2024, such amount is $507.

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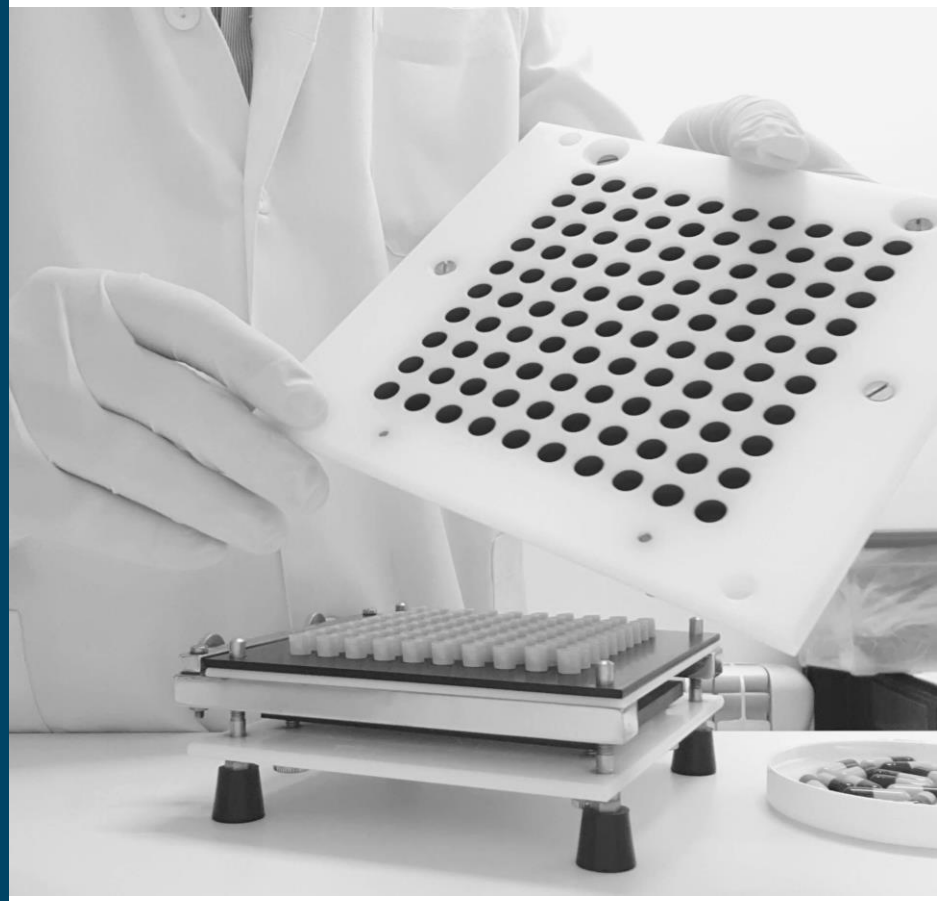
Safe Harbors



Safe Harbors

- Because of the breadth of the federal anti-kickback statute ("AKS"), the OIG has published a number of "safe harbors."
- A safe harbor is a hypothetical fact situation such that if an arrangement falls within it, then the AKS is not violated.
- If an arrangement does not fall within a safe harbor, then it does not mean that the arrangement violates the AKS. Rather it means that the arrangement needs to be carefully scrutinized under the language of the AKS, applicable case law, and other published guidance
- Five of the safe harbors are particularly relevant to DME suppliers, hospices and home health agencies.

Safe Harbors

- Small Investment Interest Safe Harbor
- Space Rental Safe Harbor
- Equipment Rental Safe Harbor
- Personal Services & Management Safe Harbor
- Employee/Employer Safe Harbor

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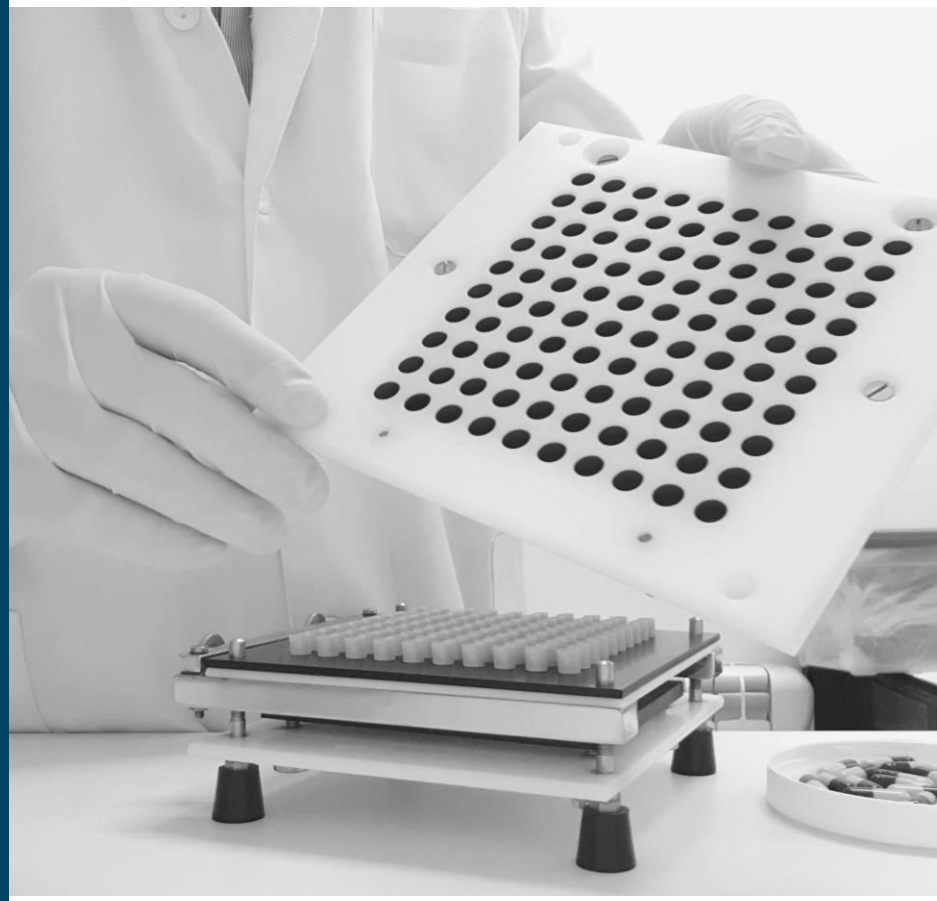
Advisory Opinions



Advisory Opinions

- A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future.
- In submitting the advisory opinion request, the provider must give to the OIG specific facts.
- In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the anti-kickback statute.

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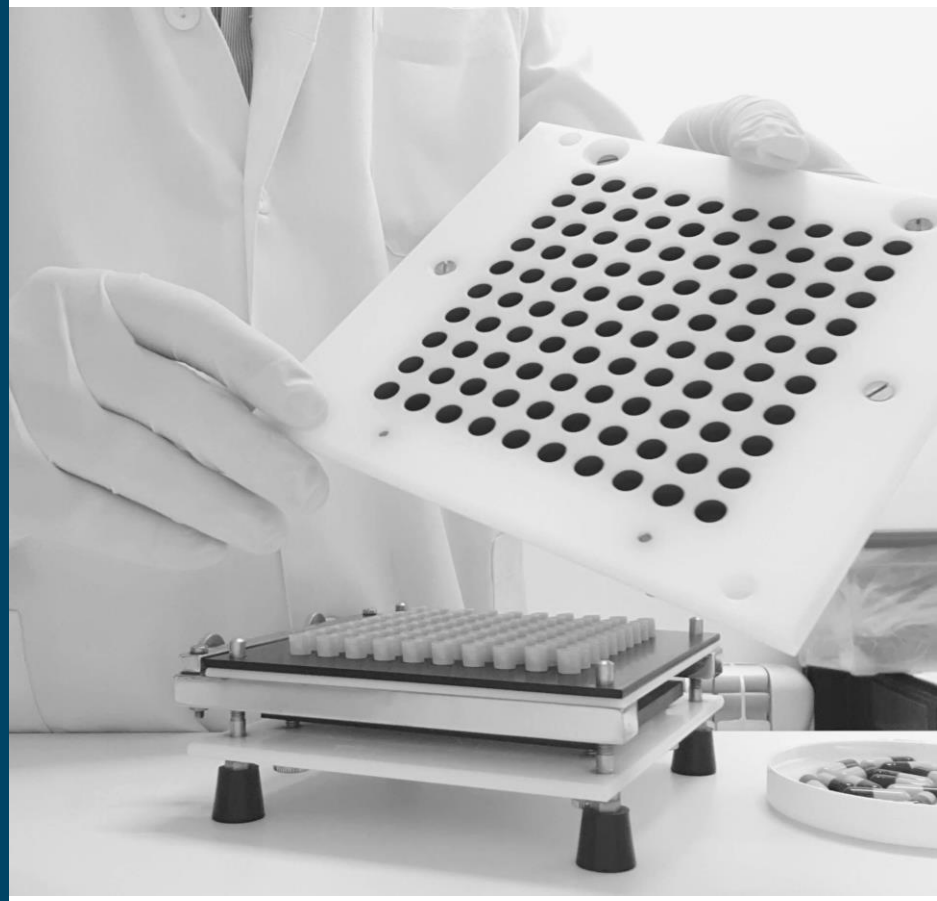
Fraud Alerts and Bulletins



Special Fraud Alerts & Special Advisory Bulletins

- From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive and educate health care providers concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry.

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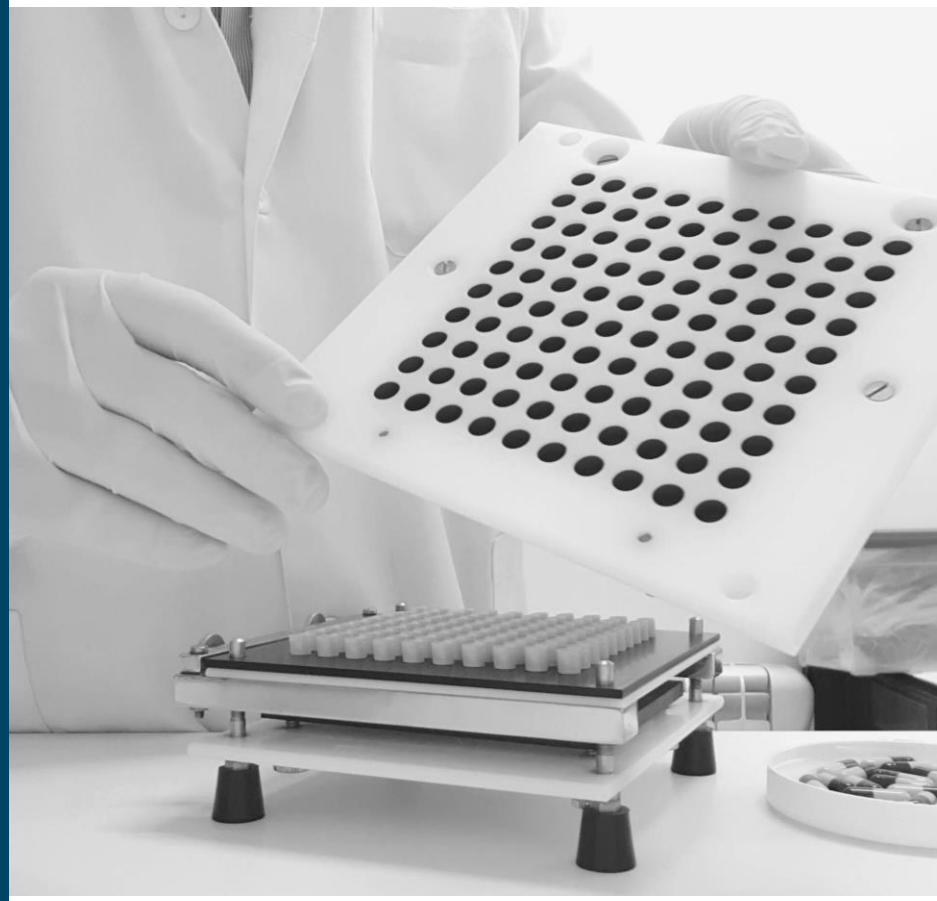
States



States

- State licensing statutes
- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, and/or self-referrals.
- Some state anti-fraud statutes only apply when the payer is a government health care program.
- Other state anti-fraud statutes that apply regardless of the identity of the payer.

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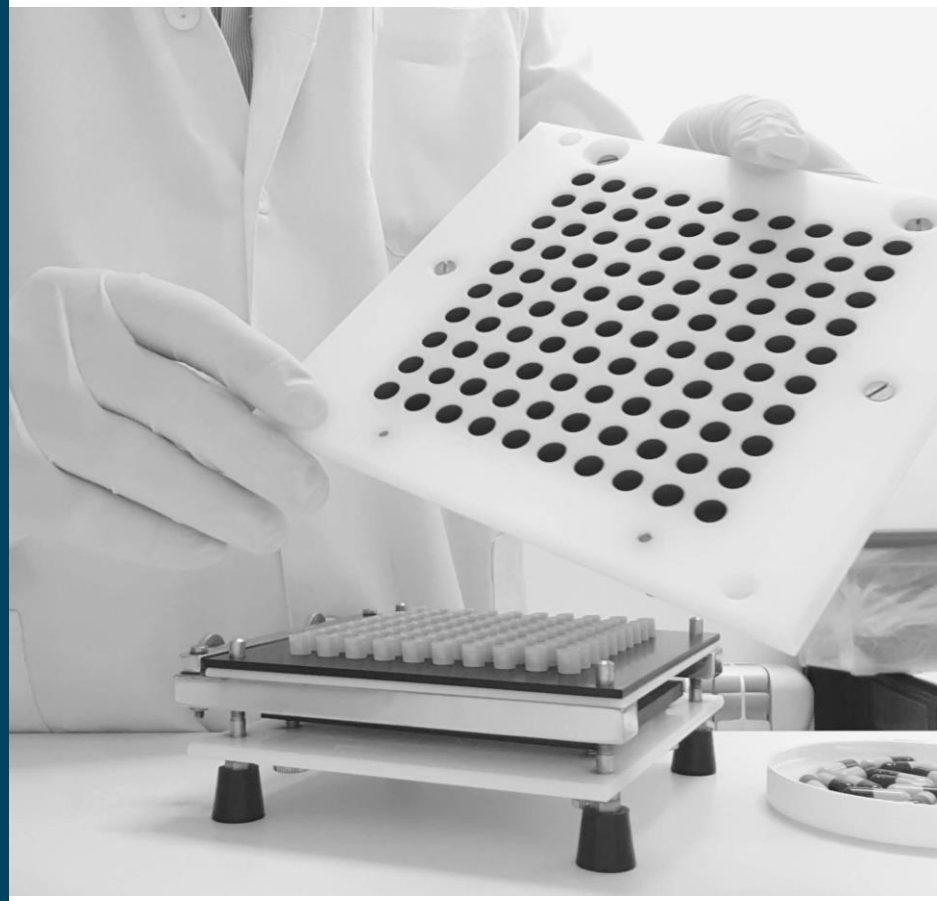
W-2 Employee vs. 1099 Independent Contractor



W-2 vs. 1099

- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents.
- In Advisory Opinion No. 06-02, the OIG stated that "[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties."
- A number of courts have held that marketing arrangements are illegal under the AKS and are, therefore, unenforceable.
- For example, the 1996 Florida Medical Development Network case involved an agreement wherein DME supplier agreed to pay an independent contractor marketing company (the "Marketer") a percentage of the DME supplier's sales in exchange for marketing its products to physicians, nursing homes, and others.

W-2 vs. 1099

- When the DME supplier breached the contract, the Marketer sued, and the DME supplier defended on the ground that the agreement was illegal under the AKS.
- A Florida appeals court agreed and affirmed the trial court's ruling, holding that the agreement was illegal and unenforceable because the Marketer's receipt of a percentage of the sales it generates for the DME supplier violated the federal AKS.

- The OIG has taken the position that even when an arrangement will only focus on commercial patients and "carve out" beneficiaries of federally-funded health care programs, the arrangement will still likely violate the AKS.

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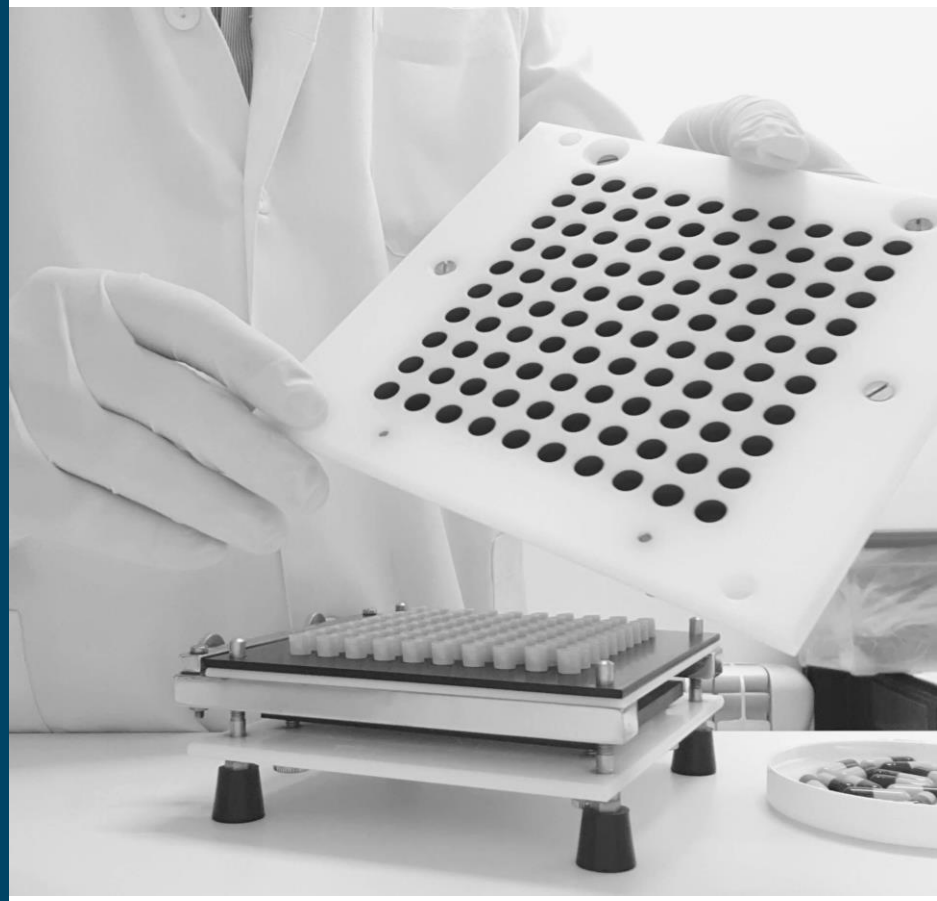
Utilization of a Marketing Company



Utilization of a Marketing Company: Be Aware of Kickback Problem

- In the real world, it is common for a business to “outsource” marketing to a marketing company.
- Unfortunately, what works in the real world often does not work in the health care universe. An example of this has to do with marketing companies.
- If a marketing company generates patients for a provider, when at least some of the patients are covered by a federal health care program (“FHCP”), then the provider cannot pay commissions to the marketing company.
- Such payment of commissions will violate the AKS.
- The only way that an independent contractor can be paid for marketing or promoting FHCP-covered items or services is if the arrangement complies with (or substantially complies with) the Personal Services and Management Contracts safe harbor.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- In Advisory Opinion No. 99-3, the OIG stated:
  - Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, “Sellers”).
  - Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by an FHCP potentially implicates the AKS, irrespective of the methodology used to compensate the agent.
  - Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee.
  - For these reasons, the OIG has a longstanding concern with independent sales agency arrangements.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated:
  - [M]any commentators suggested that we broaden the [employee safe harbor] to apply to independent contractors paid on a commission basis.
  - We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- The OIG further stated:
  - We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.

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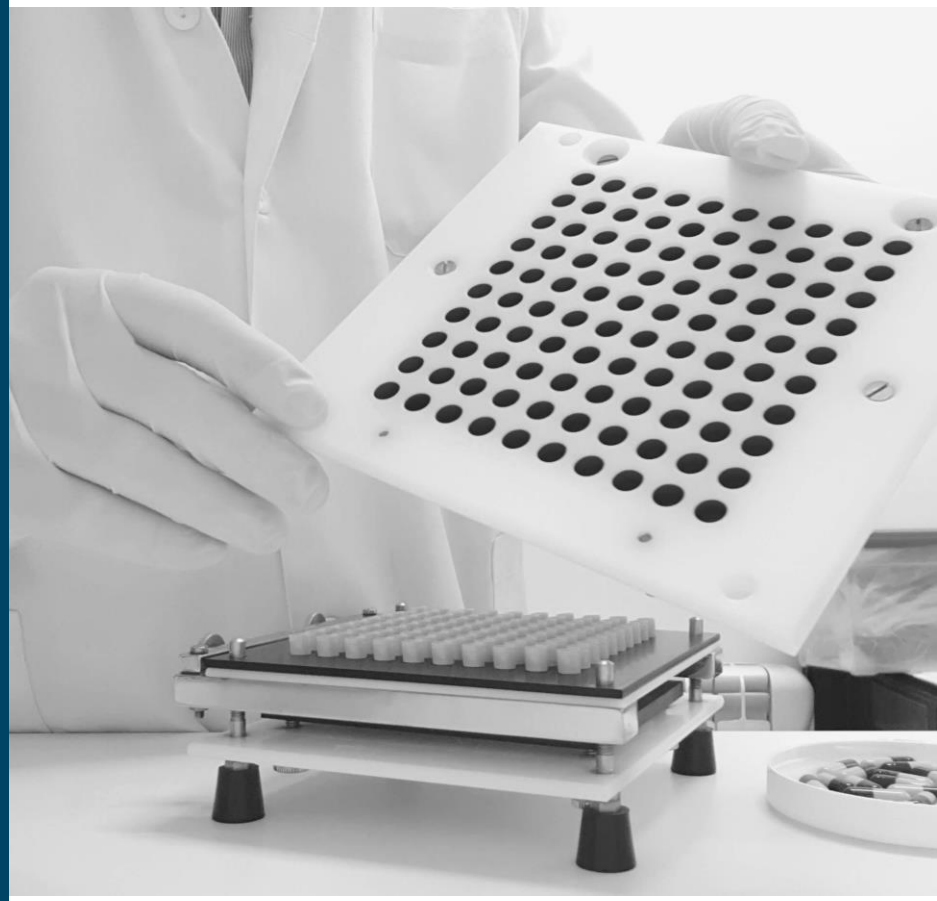
Expenditures for Physicians



Introduction

- A physician is a referral source to the provider.
- The physician refers patients who are covered by an FHCP, who are covered by commercial insurance, or desire to pay cash.
- If a provider furnishes meals, gifts and entertainment to a physician, then both the provider and the physician need to comply with the federal and state laws that govern these arrangements.

What a provider Can Spend on a Physician

- While the Stark non-monetary compensation exception allows a provider to spend up to a set amount per year (e.g., $507 in 2024) for non-cash/non-cash equivalent items for a physician, the AKS does not include a similar exception.
- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the provider to the physician violate the AKS.

What a provider Can Spend on a Physician

- In addition to complying with Stark and the AKS, the provider and the physician also need to comply with applicable state law.
- Even though the provider and the physician will need to confirm this, it is likely that compliance with the non-monetary compensation exception will avoid liability under state law.
- And so the bottom line is that a provider can provide gifts, entertainment, meals, and similar items to a physician so long as the combined value of all of these items do not exceed the annual amount set by CMS ($507 in 2024).

What a provider Can Spend on a Physician

- While the Stark non-monetary compensation exception applies to expenditures on behalf of a physician, the exception does not apply to expenditures on behalf of the physician's staff.
- In fact, Stark does not apply to the physician's staff. Expenditures on behalf of the physician's staff must be examined in light of the AKS.
- Separate from furnishing gifts and entertainment, the provider can pay the physician for legitimate services.
- For example, if the provider has a legitimate need for a Medical Director, then the provider and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the AKS and the Personal Services exception to Stark.

What a provider Can Spend on a Physician

- Another legitimate way for money to exchange hands between a provider and a physician is for the physician to rent space to the provider or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the AKS and the space rental exception to Stark. These essentially say the same thing.

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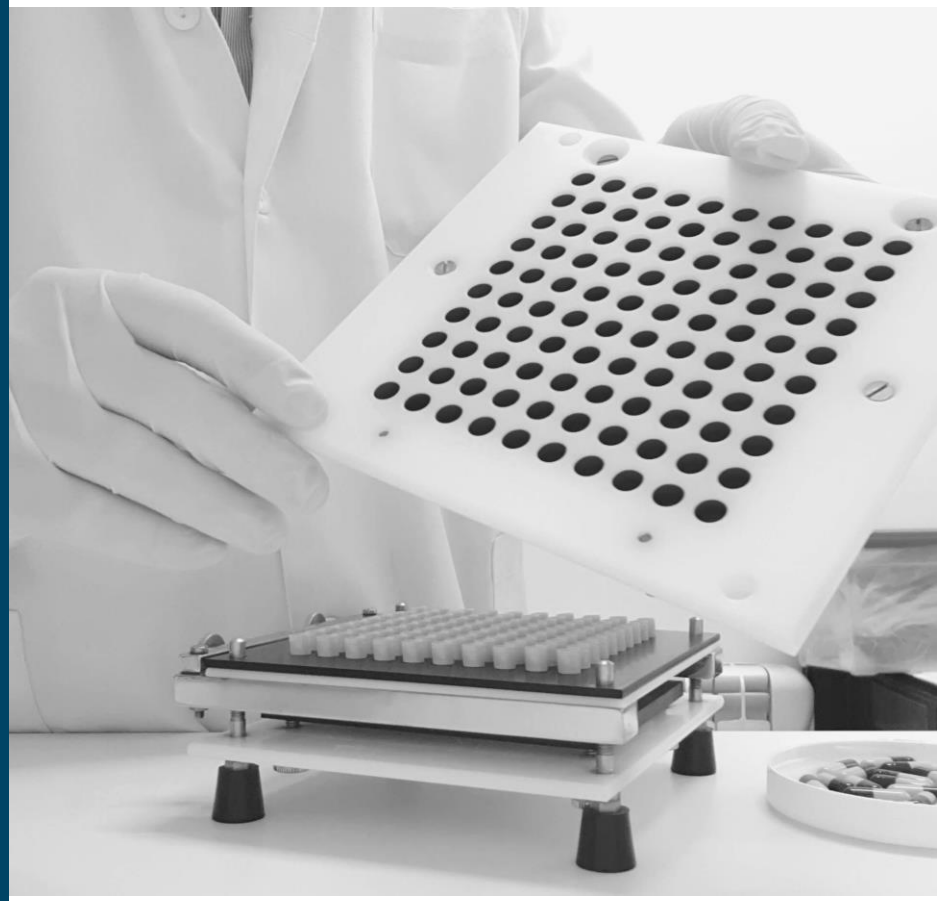
Paying Physician to Provide Education Program



Paying Physician to Provide Education Program

- It is permissible for a provider to pay a physician to present an education program if the following requirements are met:
  - The program is substantive and valuable to the audience.
  - The compensation paid to the physician is the fair market value equivalent of the time and effort the physician expended to (i) prepare for the program and (ii) present the program.

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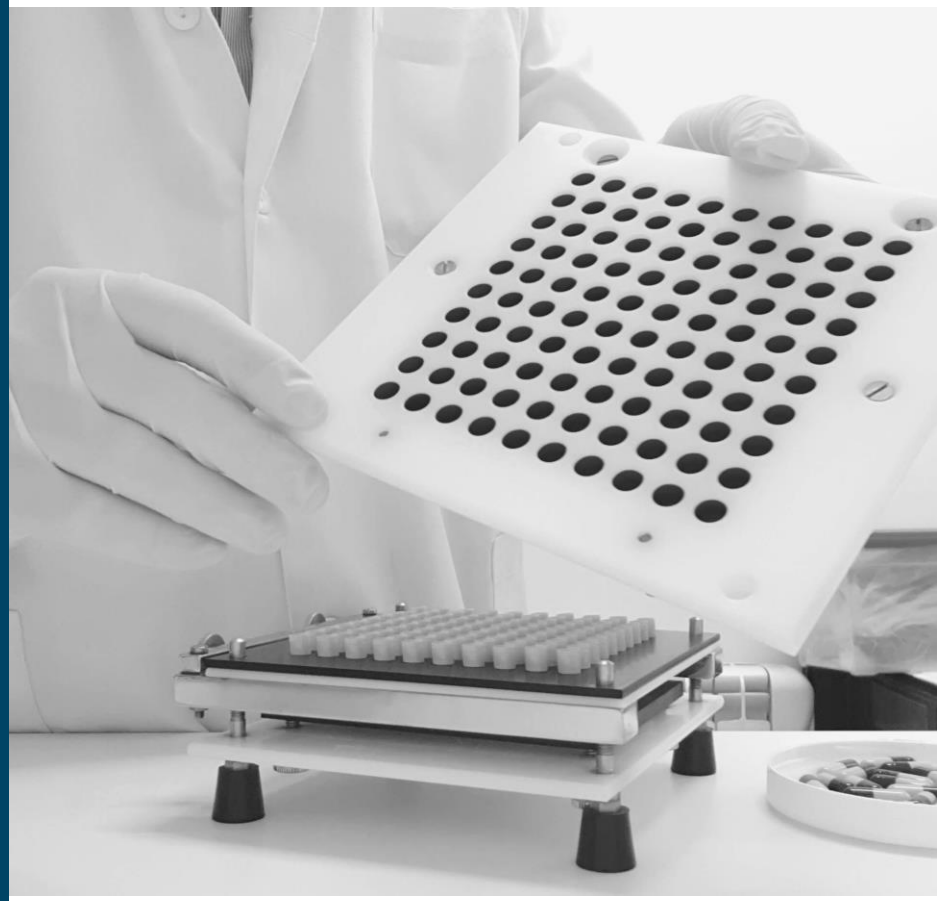
Sham Education Programs:

Guidance From A Criminal Case



Criminal Case

- Over the past couple of years, a number of executives of Insys Therapeutics, Inc. have been convicted of engaging in a large kickback scheme.
- According to a Department of Justice (“DOJ”) statement, Insys used bogus educational events as a “cover” for paying kickbacks to physicians in exchange for their increased prescriptions of Subsys®, a spray version of the opioid fentanyl.
- The DOJ alleges that Insys arranged sham “speaker programs” that were billed as gatherings of physicians to educate them about Subsys®.

Criminal Case

- In reality, according to the DOJ, the events - usually held at high-end restaurants - mostly consisted of friends and co-workers who lacked the ability to prescribe the drug, and there was no educational component.
- According to the DOJ, the “speakers” were physicians who were paid fees ranging from $1000 to several thousand dollars to attend the dinners.
- The DOJ alleged that these payments were kickbacks to the speakers “who were prescribing large amounts of Subsys® and to incentivize those [physicians] to continue to prescribe Subsys® in the future.”

Criminal Case

- Here are the “takeaways” from this criminal case:
  - Before the provider furnishes “anything of value” to a physician, the provider needs to consult with a health care attorney to ensure that the arrangement does not violate the AKS or Stark.
  - “Anything of value” can be a payment of money, it can be a trip, it can be a set of golf clubs, it can be tickets to a Springsteen concert, and it can be services that the physician would normally have to perform himself.

Criminal Case

- "Takeaways" (cont'd):
  - It is permissible for a provider to enter into a Medical Director Agreement ("MDA") with a physician who also refers FHCP patients to the provider. The MDA needs to comply with the PSMC safe harbor to the AKS and with the Stark personal services exception. Among other requirements, (i) the MDA must be in writing and have a term of at least one year, (ii) the physician must render valuable (not "made up") services to the provider, (iii) the methodology for calculating the compensation paid by the provider to the physician must be fixed one year in advance, and (iv) the compensation must be the fair market value ("FMV") equivalent of the physician's services.

Criminal Case

- "Takeaways" (cont'd):
  - If a provider is going to pay a physician to put on an education program, then it must pass the "smell test." The physician must be qualified to make the presentation, the physician must actually make the presentation, the presentation topic must be substantive and timely, the audience must be in the position of benefitting from the presentation, and the compensation to the physician must be FMV.
  - If a provider submits a claim to a government program that arises out of an improper arrangement with a physician, then the claim is "tainted" and becomes a false claim. Penalties under the federal False Claims Act can be massive.

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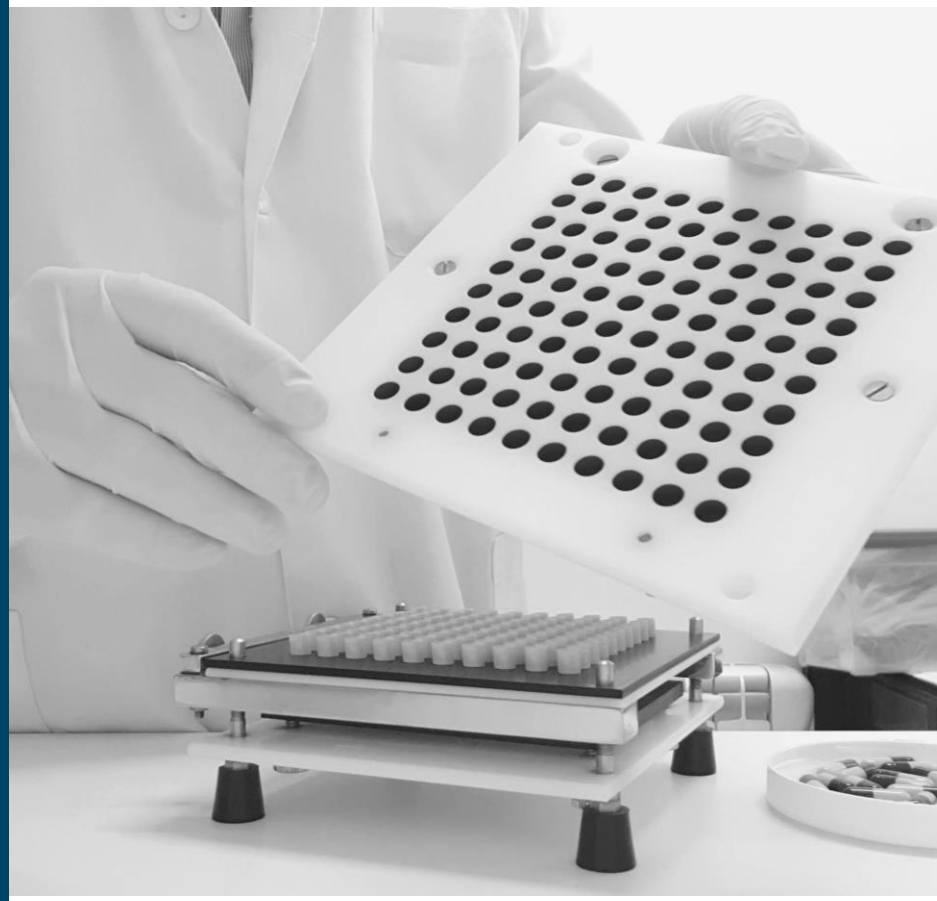
Collaboration With Hospital to Prevent Readmissions



Collaboration With Hospital to Prevent Readmissions

- Hospital Readmissions Reduction Program: if a patient is readmitted after discharge within a certain period of time, for a particular disease, then the hospital can be subjected to future payment reductions for Medicare.
- Hospital can contract with a provider to monitor/work with discharged patients so that they are not readmitted soon after being discharged.

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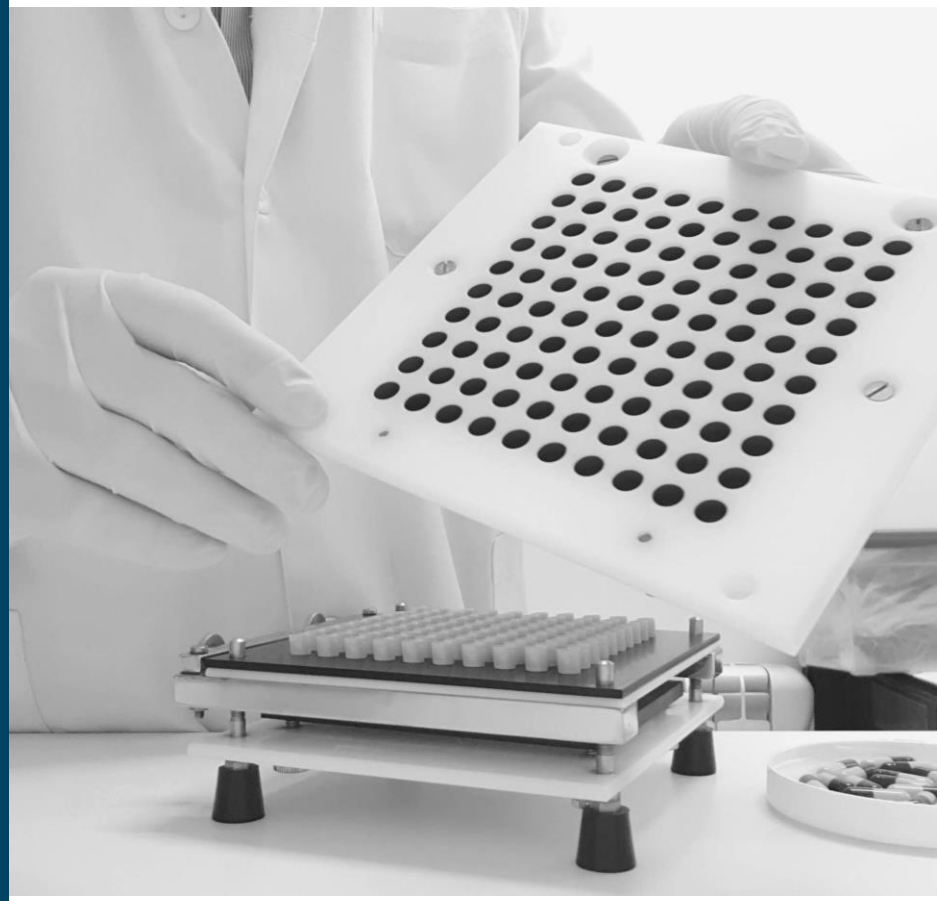
Paying for a Facility's EHR



Paying for a Facility's EHR

- Many providers work with skilled nursing facilities ("SNFs") and custodial care facilities (collectively referred to as "Facilities").
- A Facility is a "referral source" to the provider. Even though the Facility may give "patient choice," if the provider furnishes a product to a Facility patient, the law considers the patient to be a "referral" from the Facility.
- If the provider gives "anything of value" to the Facility, then the provider is at risk of being construed to be "paying for a referral" … hence, a "kickback."

Paying for a Facility's EHR

- In order for a Facility to serve Medicare and Medicaid patients, federal law imposes a number of requirements on the Facility.
- These requirements cost the Facility money in order to comply.
- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review ("DRR") on each patient.

Paying for a Facility's EHR

- Electronic medication administrative records ("eMARs") are not required for DRR; hard copy records are acceptable. Nevertheless, a Facility may desire to utilize eMAR software ("Software") for DRR and for other purposes.
- The Facility and a provider (that receives referrals from the Facility) may wish to enter into an arrangement in which the provider pays for the Software. It is at this juncture that the Facility and provider find themselves on the proverbial "slippery slope."
- Assume that the provider receives referrals from the Facility and desires to pay for the Software. By virtue of paying for the Software, the provider is providing "something of value" to the Facility … hence, the AKS is implicated.

Paying for a Facility's EHR

- The applicable safe harbor is the Electronic Health Records safe harbor.
- It states than an entity may donate software and training services "necessary and used predominantly to create, maintain, transmit, or receive electronic health records" if a number of requirements, set out in the safe harbor, are satisfied.

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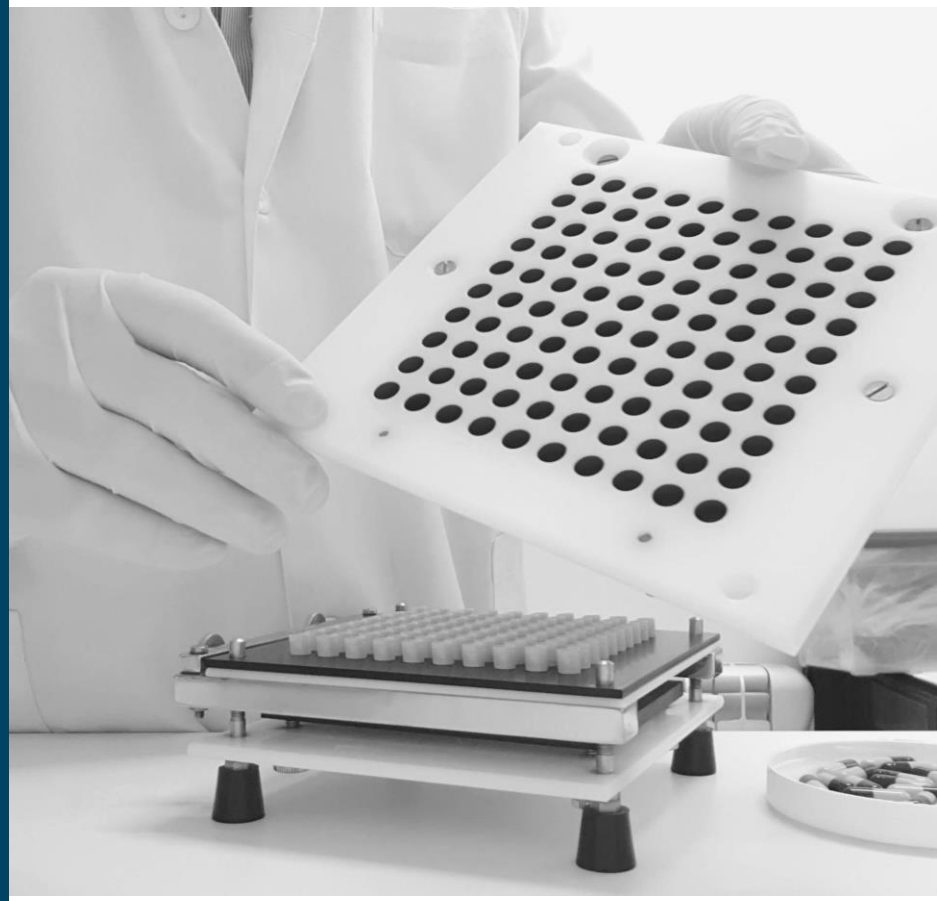
Preferred Provider Agreement



Preferred Provider Agreement

- The provider can enter into a Preferred Provider Agreement with a hospital whereby, subject to patient choice, the hospital will recommend the provider to its patients who are about to be discharged.
- The provider can enter into a similar type of Preferred Provider Agreement with a physician, long term care facility, wound care center, or other type of provider.

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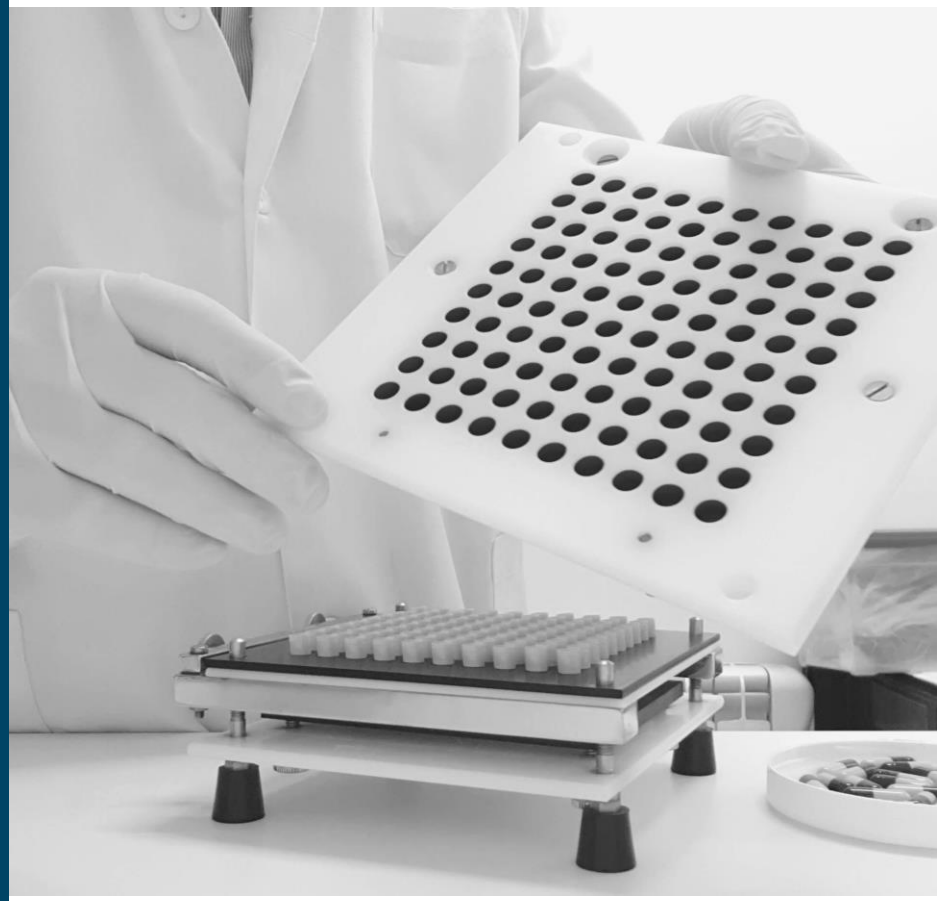
Employee Liaison



Employee Liaison

- A provider may designate an employee to be on a facility's premises for a certain number of hours each week.
- The employee may educate the facility staff regarding services the provider can offer on a post-discharge basis.
- The employee liaison may not assume responsibilities that the facility is required to fulfill.
- Doing so will save the facility money, which will likely constitute a violation of the AKS.

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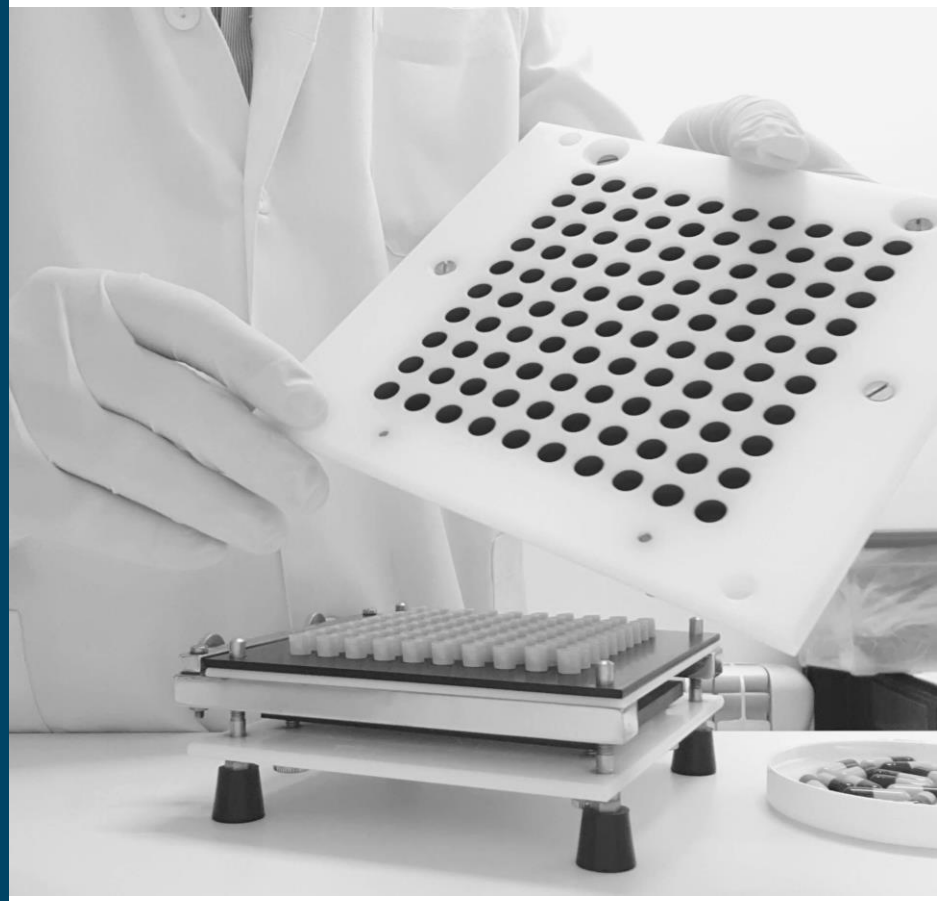
Medical Director Agreement



Medical Director Agreement

- A provider can enter into an independent contractor Medical Director Agreement ("MDA") with a physician.
- The MDA must comply with the (i) PSMC safe harbor to the AKS and (ii) the personal services exception to Stark.
- Among other requirements:
  - The MDA must be in writing and have a term of at least one year.
  - The physician must provide substantive services.
  - The methodology for calculating the compensation to the physician must be fixed one year in advance and be the FMV equivalent of the physician's services.

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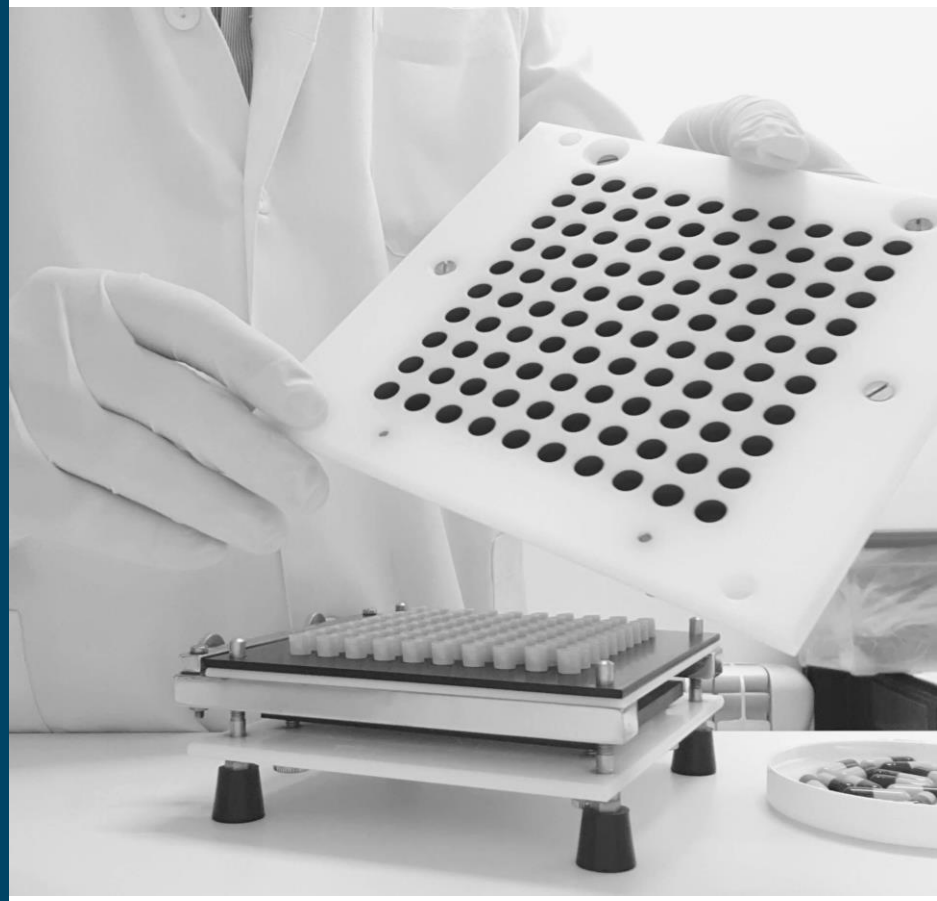
Joint Venture



Joint Venture - Definition

- A joint venture arises when two or more individuals/entities own something together.
- For example, a hospital and a DME supplier can jointly set up and own a DME company ("JV DME Company") so long as the JV DME Company is not a "sweetheart deal" for the hospital. Likewise, a hospital and a home health agency can jointly set up and own a home health agency ("JV Home Health Agency") so long as the JV Home Health Agency is not a "sweetheart deal" for the hospital.
  - Ideally, the JV will comply with the Small Investment Interest safe harbor to the AKS.
  - If the safe harbor cannot be met, then the requirements of the OIG's 1989 Special Fraud Alert ("Joint Ventures") and April 2003 Special Advisory Bulletin ("Contractual Joint Ventures") must be met.

Joint Venture with Physician

- When forming a joint venture with a physician, then not only must the arrangement comply with (i) the Small Investment Interest safe harbor or (ii) the 1989 Special Fraud Alert/April 2003 Special Advisory Bulletin, but the arrangement must comply with Stark. For example:
  - If the JV Home Health Agency is located in a rural area, then the physician can refer Medicare/Medicaid patients to the JV Home Health Agency.
  - If the JV Home Health Agency is not located in a rural area, then the physician cannot refer Medicare/Medicaid patients to the JV Home Health Agency.

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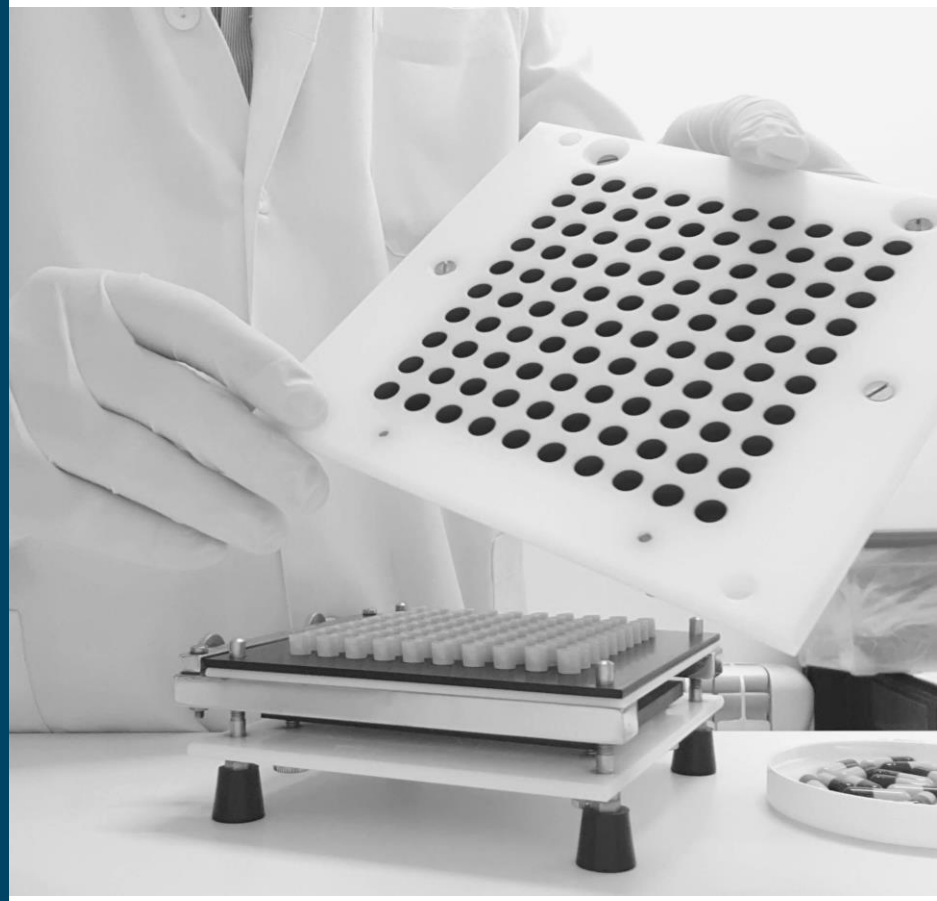
Working With Physicians in Rural Areas



Stark Rural Provider Exception

- In entering into an arrangement with a physician in a rural area, the provider needs to focus on the rural provider exception.
- The rural provider exception states that an ownership interest by a physician in a rural provider is not considered a “financial relationship” under Stark.

Stark Rural Provider Exception

- Rural providers are defined as those that furnish at least 75% of the designated health services they provide to residents of a “rural area.”
- Thus, whether this exception applies depends on whether at least 75% of the patients that the provider’s services are located within a “rural area.”
- “Rural area” is defined as “an area that is not an urban area as defined in 42 CFR 412.62(f)(1)(ii) which states that “the term urban area means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget ….”

Stark Rural Provider Exception

- Therefore, any area that is not an MSA or a NECMA is considered to be a “rural area.”
- So long as no less than 75% of the products and services that the provider furnishes is to patients in a rural area, the rural provider exception applies to the provider, regardless of where the provider is located.
- The current list of MSAs can be found on the U.S. Census Bureau website. A town might fall within a Micropolitan Statistical Area, which is defined as an urban cluster of at least 10,000 but less than 50,000 people.

Stark Rural Provider Exception

- In regard to whether a Micropolitan Statistical Area could be considered a “rural area” under the definition of Stark, the Stark II, Phase III implementation final rule states: “Micropolitan Statistical Areas are not within MSAs; thus, for purposes of the physician self-referral rules, Micropolitan Statistical Areas are not considered urban and are, therefore, rural areas.
- So long as the provider satisfies the Stark “rural provider” exception, then a physician can have an ownership interest in the provider and can refer Medicare, Medicare Advantage, Medicaid, and Medicaid Managed Care patients to the provider.

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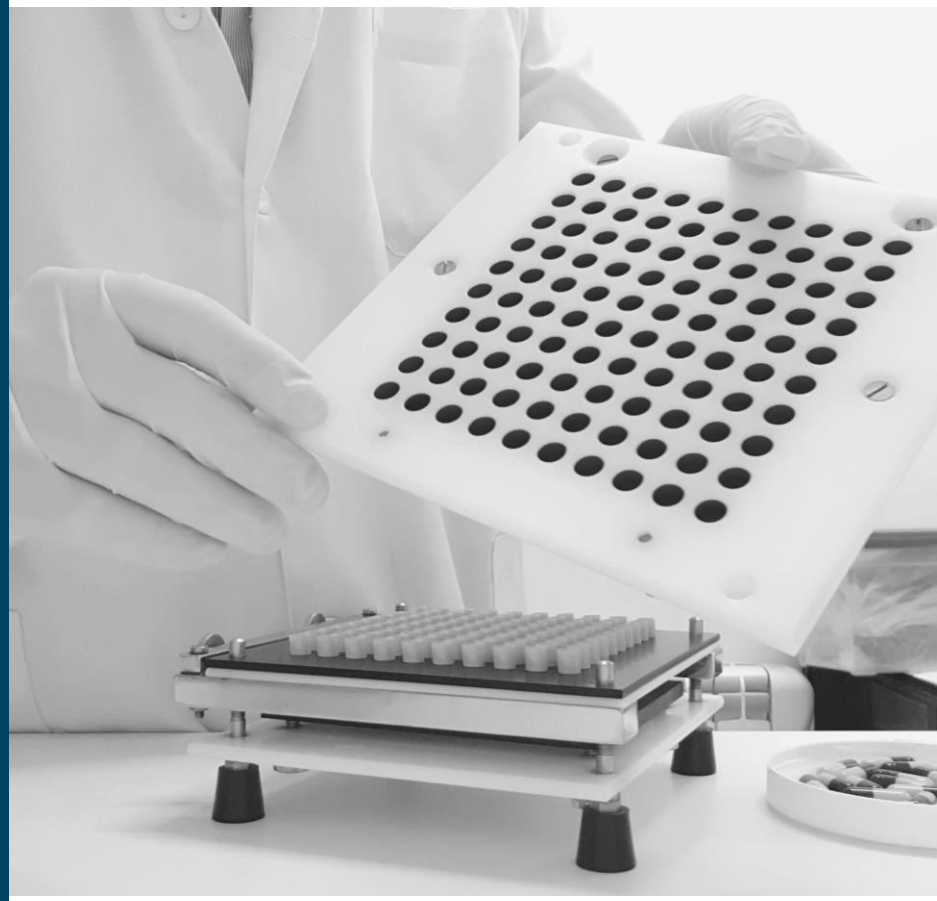
Annual Wellness Visits (“AWVs”)/Remote Patient Monitoring (“RPM”)/ Chronic Care Management (“CCM”)



AWVs/RPM/CCM

- Assume that the physician (i) has AWVs with patients, (ii) provides RPM to patients and/or (iii) provides CCM to patients.
- Assume that the provider assists the physician in (i) conducting AWVs and (ii) providing RPM and CCM.
- It is the physician that is paid for AWVs, RPM and CCM. If the provider assists with AWVs, RPM and CCM for free, then such assistance constitutes “something of value” to a referral source, thereby implicating the AKS and Stark.
- In order to avoid AKS and Stark problems, the physician must pay FMV compensation to the provider for the provider’s services.

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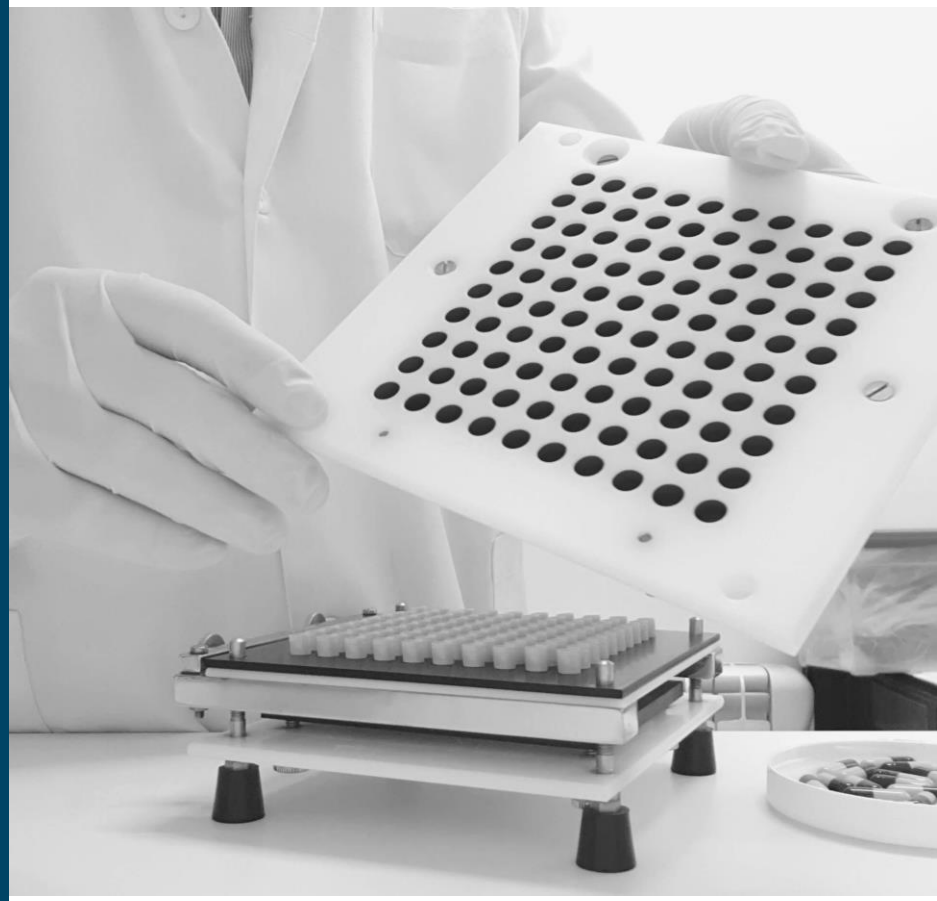
Education Workshops



Education Workshops

- The physician can set up times for the provider to send representatives to the physician's office to educate the physician's employees regarding (i) products and services offered by the provider and (ii) how the provider's products/services can treat specific conditions.
- The physician can set up times for the provider to send representatives to the physician's office to present workshops to the physician's patients who have conditions that can be treated by the provider's products and services.

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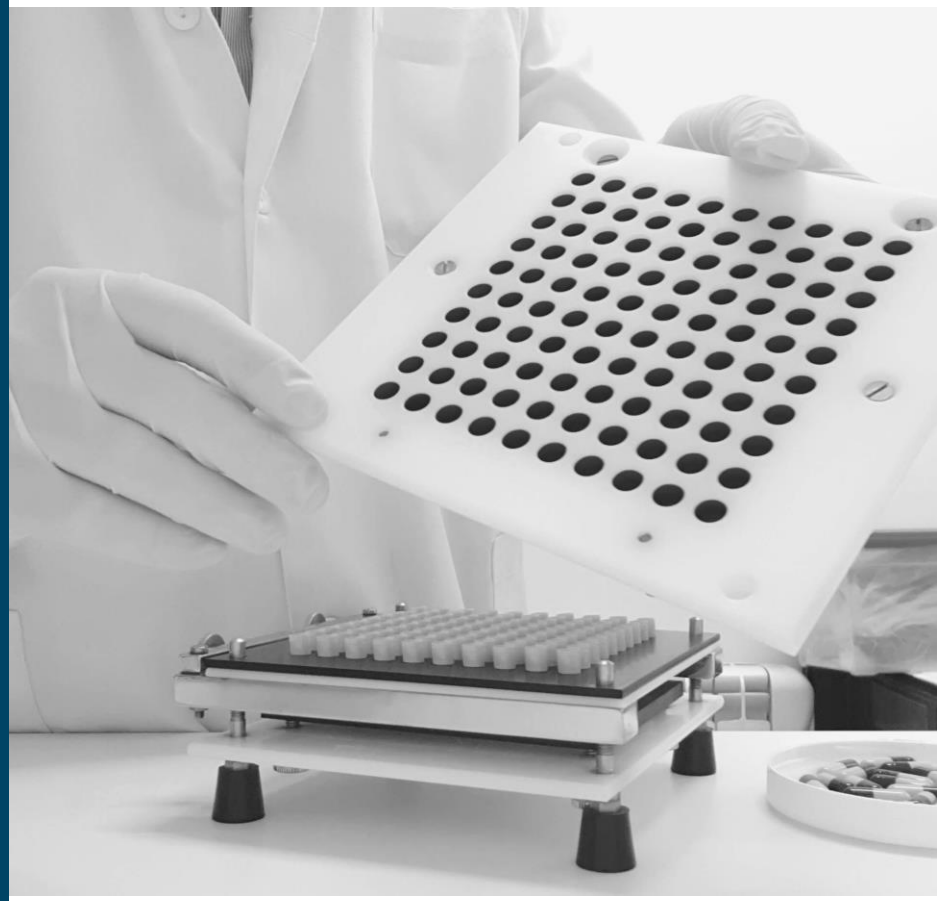
Sponsoring Physicians at Educational Events



Hypothetical Scenarios

- Scenario #1
  - Dr. Smith refers FHCP patients to ABC Home Health/DME (“ABC”). Dr. Smith requests ABC to sponsor his trip to a conference in Palm Springs.
- Scenario #2
  - ABC is holding its annual meeting in Aspen in July for its employees. ABC asks Dr. Jones to speak at the annual meeting. Dr. Jones refers FHCP patients to ABC. In so doing, ABC offers to (i) pay Dr. Jones for his time in preparing for and presenting his program and (ii) reimburse Dr. Jones for his travel expenses.

Hypothetical Scenarios

- Analysis of Scenario #1
  - Dr. Smith refers FHCP patients to ABC. If ABC compensates Dr. Smith, then the transaction creates a financial relationship between Dr. Smith and ABC. As such, the arrangement violates Stark unless an exception is met.
  - ABC would like to reimburse Dr. Smith for his expenses in attending the Palm Springs conference. The Stark nonmonetary compensation exception only applies to compensation paid to a physician in the form of items or services, not cash or cash equivalents. Further, Dr. Smith reached out to ABC to request the compensation. The exception does not apply if the physician solicits an entity for the compensation. Accordingly, the arrangement does not fall within the Stark nonmonetary compensation exception.

Hypothetical Scenarios

- Analysis of Scenario #1
  - This scenario also would likely not meet the Stark personal services exception or the Stark FMV exception. Both exceptions require the physician to provide a service to the entity. Dr. Smith's attendance at the Palm Springs conference does not constitute a "service" for ABC.
  - Dr. Smith refers FHCP patients to ABC, and if ABC agrees to cover some of Dr. Smith's expenses to attend the Palm Springs conference, then Dr. Smith is receiving renumeration … thereby implicating the AKS. To avoid problems under the AKS, the arrangement would need to meet an AKS safe harbor. Because Dr. Smith is not providing a service to ABC, the PSMC safe harbor is not met.

Hypothetical Scenarios

- Analysis of Scenario #2
  - Like the first arrangement, Dr. Jones refers FHCP patients to ABC and a financial relationship will form if ABC compensates Dr. Jones. As such, the arrangement implicates Stark unless an exception is met.
  - Unlike the first arrangement, Dr. Jones is providing ABC a service by speaking at an ABC sponsored meeting attended by ABC's employees. The purpose of his presentation is to educate and train the ABC employees on clinical and related issues.

Hypothetical Scenarios

- Analysis of Scenario #2
  - Since Dr. Jones is providing ABC a service, the arrangement can be structured to fall under the Stark personal services exception. The written agreement must include: (i) a detailed description of Dr. Jones's presentation, how it will be given, and the intended audience; (ii) a set compensation amount that is FMV; and (iii) an agreement term for not less than one year. The exception also requires that the service be reasonable and necessary for the legitimate business purposes of the arrangement.

Hypothetical Scenarios

- Analysis of Scenario #2
  - ABC's arrangement may also fall within the Stark FMV exception. It is reasonable to assume that Dr. Jones's presentation will be commercially reasonable and furthers a legitimate business purpose. Note that the FMV exception also requires compliance with the AKS. The arrangement can be structured to comply with (or substantially comply with) the PSMC safe harbor. This is so long as the arrangement is put in writing and the agreement includes the safe harbor's requirements.

Hypothetical Scenarios

- Analysis of Scenario #2
  - To reduce the risk of an enforcement action, ABC should include significant detail on the amount of time Dr. Jones will be paid to prepare and give his presentation. For example, the agreement can require Dr. Jones to submit his presentation for approval by ABC prior to the Aspen meeting. The agreement should also limit Dr. Jones's expenses to reasonable amounts and require Dr. Jones to submit an invoice of his time and expenses to ABC. This will allow ABC to review Dr. Jones's expenses and ensure that his costs are reasonable and within the compensation amount set forth in the agreement. Only after ABC's review and approval of the invoice should ABC compensate Dr. Jones.

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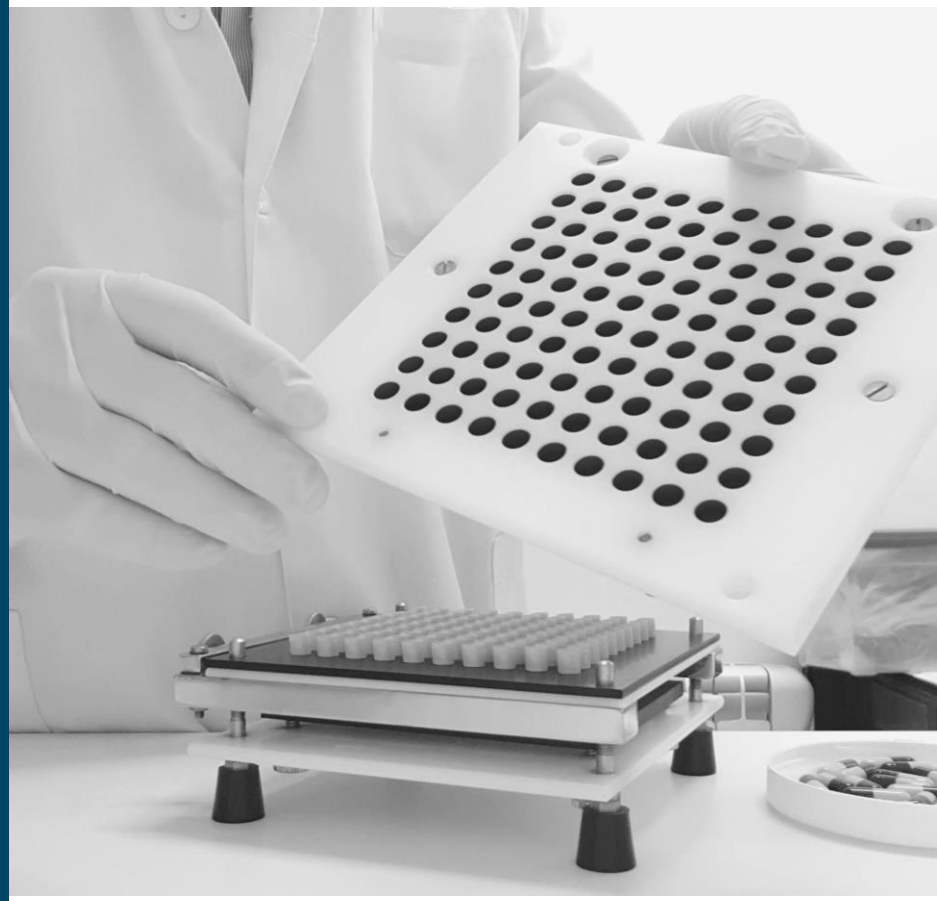
Sham Telehealth Arrangements



Sham Telehealth Arrangements

- Providers are aggressively engaged in marketing and it is not uncommon for a provider to provide products and services to patients residing in multiple states.
- When a provider is marketing to patients in multiple states, the provider may run into a “bottleneck.”
- This involves the patient’s local physician. A patient may desire to obtain a product from the out-of-state provider, but it is too inconvenient for the patient to drive to his physician’s office.

Sham Telehealth Arrangements

- Or if the patient is seen by his local physician, the physician may decide that the patient does not need the product or service and so the physician refuses to sign a prescription/order.
- Or even if the physician does sign an order, he may be hesitant to send the order to an out-of-state provider.
- In order to address this challenge, some providers are entering into arrangements that will get them into trouble.
- This has to do with “telehealth” companies.

Sham Telehealth Arrangements

- A typical telehealth company has contracts with many physicians who practice in multiple states.
- The telehealth company contracts with and is paid by (i) self-funded employers that pay a membership fee for their employees, (ii) health plans, and (iii) patients who pay a per visit fee.
- Where a provider will find itself in trouble is when it aligns itself with a telehealth company that is not paid by employers, health plans and patients – but rather – is directly or indirectly paid by the provider.

Sham Telehealth Arrangements

- Here is an example: provider purchases leads from a marketing company … the marketing company sends the leads to the telehealth company … the telehealth company contacts the leads and schedules audio or audio/visual encounters with physicians contracted with the telehealth company … the physicians issue prescriptions/orders … the telehealth company sends the orders to the provider … the marketing company pays compensation to the telehealth company for its services in contacting the leads and setting up the physician appointments … the telehealth company pays the physicians for their patient encounters … the provider furnishes the product or service to the patient … the provider bills (and gets paid by) an FHCP.

Sham Telehealth Arrangements

- There can be a number of permutations to this example, but you get the picture.
- Stripping everything away, the provider is paying the ordering physician.
- To the extent that a provider directly or indirectly pays money to a telehealth physician, who in turn writes a prescription/order for products/services that will be furnished by the provider, the arrangement will likely be viewed as remuneration for a referral (or remuneration for “arranging for” a referral).

Sham Telehealth Arrangements

- If the payer is an FHCP the arrangement will likely violate the AKS.
- If the payer is the state Medicaid program, the arrangement will likely violate both the AKS and the state anti-kickback statute.
- If the payer is a commercial insurer, the arrangement may violate a state statute.

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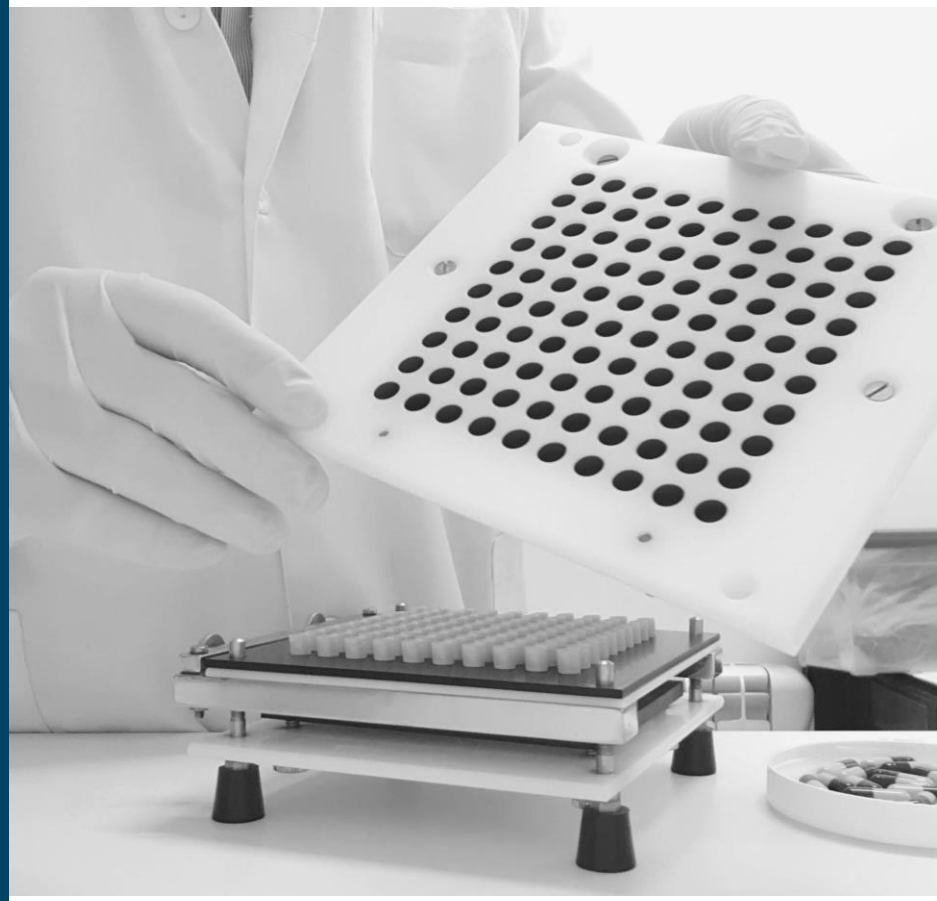

Summary:

Dos and Don’ts of Setting Up Referral Network

“Dos” of Setting Up Referral Network

- **Use of Employees** - The provider can pay base salaries plus discretionary bonuses to full-time or part-time bona fide employees.
- **Use of Independent Contractors** - The provider can compensate 1099 independent contractors for marketing to FHCP patients so long as the arrangement complies with the PSMC safe harbor to the AKS.
- **Expenditures for Physicians** - The provider can spend up to a certain amount per year ($452 in 2022) on a physician for non-cash/non-cash equivalent items.

“Dos” of Setting Up Referral Network

- **Expenditures for Physicians' Staffs, Hospital Discharge Planners, and Other Referral Sources** - It is permissible for the provider to provide non-cash/non-cash equivalent items to non-physicians so long as the amount spent is modest. For example, while it is permissible for the provider to sponsor lunch (with an in-service) for the physician's staff twice a year, it is not permissible for the provider to sponsor lunch every month. In determining whether an arrangement amounts to a kickback, the "duck" test applies: "If it looks like a duck, walks like a duck, and sounds like a duck, then it is a duck."

“Dos” of Setting Up Referral Network

- **Medical Director Agreement** - It is permissible for a provider to enter into a 1099 independent contractor MDA with a referring physician so long as the MDA complies with the PSMC safe harbor to the AKS and the personal services exception to Stark. The safe harbor and exception essentially say the same thing.
- **Employee Liaison** - The provider can place an employee liaison at a facility so long as the liaison does not perform services that the facility would normally have to perform.

“Dos” of Setting Up Referral Network

- **Joint Venture With Referral Source (e.g., Hospital)** - A hospital and a provider can jointly own a health care entity. Preferably, the JV will comply with the Investment Interest Safe Harbor to the AKS. If this is not possible, then the JV needs to comply with the OIG's 1989 Special Fraud Alert entitled "Joint Ventures" and the OIG's April 2003 Special Advisory Bulletin entitled "Contractual Joint Ventures." In essence, these say that a JV cannot be a "sweetheart deal" for the hospital.

“Don’ts” of Setting Up Referral Network

- **Use of Independent Contractors** - If a 1099 independent contractor is generating FHCP patients for the provider, then the provider cannot pay percentage compensation to the independent contractor. Rather, the compensation must comply with the PSMC safe harbor to the AKS. The provider and independent contractor cannot engage in a "carve out" arrangement in which the provider pays (i) the independent contractor percentage compensation for commercial insurance patients and (ii) nothing for FHCP patients.

“Don’ts” of Setting Up Referral Network

- **Expenditures for Physicians** - The provider cannot give cash or cash equivalents (e.g., gift cards) to physicians. The provider cannot give non-cash/non-cash equivalent gifts to physicians that exceed the annual amount that by CMS (e.g., $452 in 2022).
- **Expenditures for Non-Physician Referral Sources** - The provider should not spend more than a modest amount on non-cash/non-cash equivalent items (e.g., meals with an in-service) on physicians' staffs, hospital discharge planners, and other referral sources.
- **Medical Director Agreements** - The compensation paid by the provider to a Medical Director cannot vary based on the number of referrals from the Medical Director to the provider. The services by the Medical Director must be important and substantive, not "made up."

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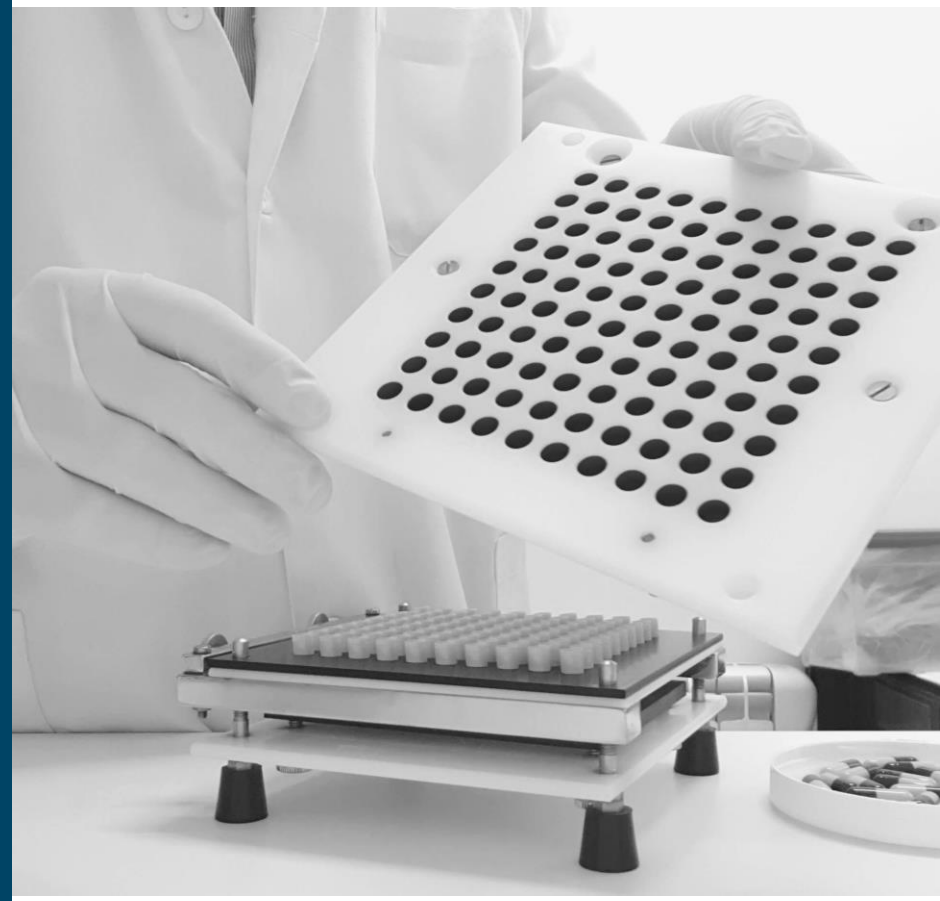

Thank you

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