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What's trending? Conflict of Interest (COI)

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January 2020

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What's trending | Objectives

We have three objectives for today's discussion. During this presentation, you can expect to...

1

Understand the recent activities in the media around conflicts of interest and why this matters to your organization

2

Review pertinent regulatory and ethical obligations relevant to healthcare organizations

3

Learn about standard practices / improvements being made in healthcare organizations and their conflict of interest programs

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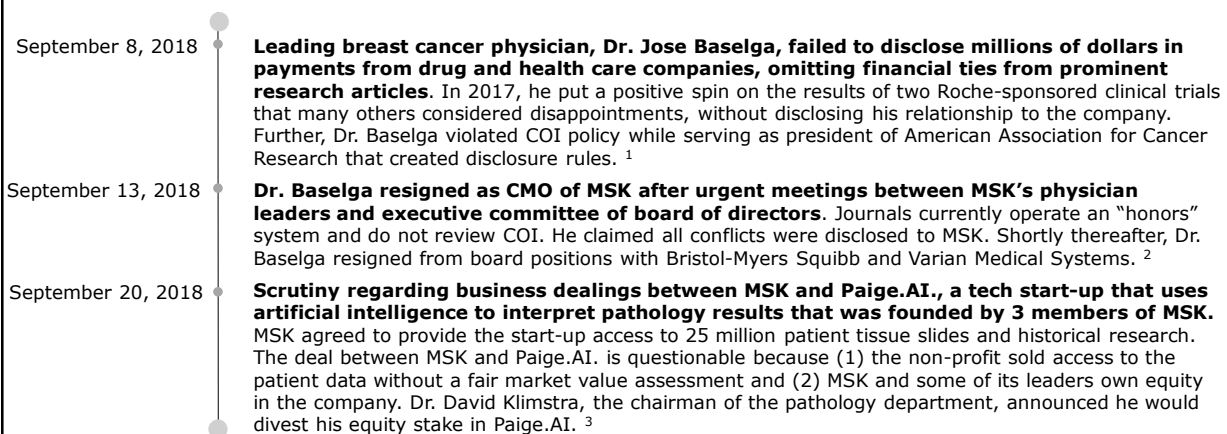
Recent media attention

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What's trending | MSK in the headlines.....

In late 2018, it was discovered that the Chief Medical Officer (CMO) of Memorial Sloan Kettering (MSK) failed to disclose significant financial interests (SFI) related to research triggering a cascade of COI activities



1. <https://www.nytimes.com/2018/09/08/health/jose-baselga-cancer-memorial-sloan-kettering.html?action=click&module=inline&pgtype=Article®ion=Footer>
2. <https://www.nytimes.com/2018/09/13/health/jose-baselga-cancer-memorial-sloan-kettering.html?module=inline>
3. <https://www.propublica.org/article/sloan-kettering-cozy-deal-with-start-up-paige-ai-ignites-new-uproar>

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What's trending | MSK in the headlines.....

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- September 21, 2018 • **MSK launched a COI task force** announcing the task force will be chaired by the MSK Chief Risk Officer, and will include other MSK physicians and external COI specialist as members of the task force. ⁴
- September 25, 2018 • **MSK changed the focus of its annual fundraising campaign** that was originally centered around harnessing big data to use artificial intelligence in cancer research. Due to the exclusive deal between MSK and Paige.AI (the aforementioned AI company), MSK pathologists believe their work would be commercialized for private gains and patients were not correctly informed that images of their tissue were being used. As a result, a new campaign was announced with a focus on patient care. ⁵
- September 29, 2018 • **Dr. Gregory Raskin, the MSK VP over hospital ventures with for-profit companies, was required to turn over nearly \$1.4 million to the hospital after the Y-mAbs IPO.** As a board member for and stockholder of Y-mAbs Therapeutics, Dr. Raskin approved the deal with MSK. As a response, MSK prohibited accepting personal compensation when representing MSK on corporate boards. MSK had equity stake in Y-mAbs Therapeutics worth \$73 million just after IPO. ⁶
- October 1, 2018 • **MSK announced plans to change internal policies stating that any potential equity that could be attained by employees appointed as MSK-designees to outside boards will be returned to the institution and dedicated to research.** A transcript of an internal meeting regarding the recent discoveries was inadvertently e-mailed to NYT reporter. US Representative Dingell asked questions regarding the deal with Paige.AI. ⁷

4. <https://www.lobud.com/story/news/health/2018/09/21/memorial-sloan-kettering-conflict-interest-task-force/1381042002/>
5. <https://www.propublica.org/article/memorial-sloan-kettering-cancer-center-switches-focus-on-fundraising-as-problems-mount>
6. <https://www.propublica.org/article/facing-crisis-sloan-kettering-tells-exec-to-hand-over-profits-from-biotech>
7. <https://www.lobud.com/story/news/health/2018/10/01/memorial-sloan-kettering-conflict-interest-response/1485431002/>

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What's trending | MSK in the headlines.....

In late 2018, it was discovered that the Chief Medical Officer (CMO) of Memorial Sloan Kettering (MSK) failed to disclose significant financial interests related to research triggering a cascade of COI activities

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- October 2, 2018 • **MSK's President and CEO Craig Thompson, MD, resigned from boards pharmaceutical companies** MSK announced the decision to give physicians a greater voice in operations. ⁸
- October 12, 2018 • **MSK CEO and 2 physicians published corrections to 7 articles disclosing relationships with pharma companies.** MSK spokesperson called financial disclosure reporting "a massive, industry-wide problem." ⁹
- January 11, 2019 • **After discussion as to whether the issue was the conflict or failure to disclose, MSK announced a permanent series of reforms** in which top executives were barred from serving on boards for drug and health care companies, board members may no longer invest in start-ups that MSK helped found, and hospital employees on corporate boards may not accept personal compensation or stock options. ¹⁰
- April 4, 2019 • **MSK made the results of outside review available to the public** with new initiatives to create a Board Committee to oversee conflicts, new/modified disclosure requirements, lower income thresholds, regular audits, tighter controls for governance of MSK spin-offs, pre-employment vetting of financial interests, clear "guard rails" for external activities, expand the definition of covered persons, and more. ¹¹

8. <https://www.beckershospitalreview.com/hospital-management-administration/memorial-sloan-kettering-ceo-resigns-from-merck-s-board.html>
9. <https://www.nytimes.com/2018/10/12/health/memorial-sloan-kettering-cancer-disclosure.html>
10. <https://www.propublica.org/article/memorial-sloan-kettering-curbs-executives-ties-to-industry-after-conflict-of-interest-scandals>
11. <https://www.propublica.org/article/memorial-sloan-kettering-leaders-violated-conflict-of-interest-rules>

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What's trending | UMMS in the headlines.....

In March 2019, a longstanding issue with lack of transparency due to unenforced laws resurfaced with the sponsorship of a new bill to require the University of Maryland Medical System (UMMS) board to increase transparency with the public

- March 13, 2019 • **A bill sponsored by Maryland Senator Jill Carter advocates for increased controls over how publicly funded hospitals conduct business.** Members of the UMMS board of directors are unpaid for their services but receive indirect financial gains from contracts with their businesses which provide goods and services to UMMS. ¹²
- April 7, 2019 • **General Assembly passes the bill prohibiting board members from holding no-bid contracts with UMMS and announces an audit of UMMS contracts.** Further, the bill requires transparency of annual disclosure forms and forces all UMMS board members to resign but may seek reappointment. ¹³
- April 26, 2019 • **UMMS's President and Chief Executive, Robert Chrencik, resigns and Mayor Pugh (and UMMS Board Member) takes a leave of absence from her role as mayor after her home was searched by Federal agents** regarding a book deal between UMMS and the mayor valued at \$500,000. ¹⁴
- June 13, 2019 • **Results of an outside review were made public, attributing much of the blame to Chrencik.** The same day, four board members, who were required to step down by the General Assembly in March due to professional contracts providing services to UMMS, were reappointed to their roles on the board, raising many questions. ¹⁵

12. <https://www.baltimoresun.com/politics/bs-md-umms-legislation-20190312-story.html>

13. <https://www.baltimoresun.com/news/investigations/bs-md-umms-pla-20190326-story.html>

14. https://www.washingtonpost.com/local/md-politics/umms-chief-executive-resigns-one-day-after-federal-agents-search-pugh-office-home/2019/04/26/ac5b2a86-6849-11e9-a1b6-b29b90efa879_story.html

15. https://www.washingtonpost.com/local/md-politics/flabbergasted-lawmakers-condemn-self-dealing-at-umms-outlined-in-report/2019/06/13/66235756-8de1-11e9-adf3-f70f78c156e8_story.html

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What's trending | UNC Health in the headlines.....

In August 2019, another reputable health system was found to have an executive with undisclosed significant financial conflicts of interest led to the discovery of additional COI violations

- August 6, 2019 • **Dr. William Roper, current UNC President and former CEO of UNC Health System, failed to disclose significant financial interest on the North Carolina Statement of Economic Interest (SEI) forms.** According to a local news source, this failure to disclose dates back to 2011 for millions of dollars from board roles with two major life science and health care companies, DaVita, Inc and Express Scripts. Further investigation found Express Scripts was the pharmacy benefit manager for the State Health Plan and DaVita, Inc. is promoted on the website of the UNC Kidney Center. ¹⁶
- August 7, 2019 • **University of North Carolina's Board Chairman, Harry Smith, publicly stated he was not concerned** over reports Dr. Roper failed to disclose potential conflicts of interest on state ethics forms and that "forms can be complicated." ¹⁷
- November 8, 2019 • **Continued investigations into the Board found other UNC Health Care Board Members failed to disclose financial interests for travel to meetings.** The 2019 North Carolina SEI form includes travel under "scholarship - a grant-in-aid, either direct or indirect, to attend a conference, meeting, or similar event, including tuition, travel, lodging, meals, and other similar expenses." ^{18, 19}

16. <https://www.wbtv.com/2019/08/06/unc-system-head-former-unc-health-care-ceo-didnt-disclose-corporate-board-seats-that-paid-millions-ethics-forms/>

17. <https://www.beckershospitalreview.com/hospital-management-administration/forms-can-be-complicated-unc-board-says-over-health-system-ceo-s-failure-to-disclose-conflicts-of-interest.html>

18. <https://www.beckershospitalreview.com/hospital-management-administration/investigation-finds-unc-health-care-board-shuttles-members-to-meetings-by-private-jet.html>

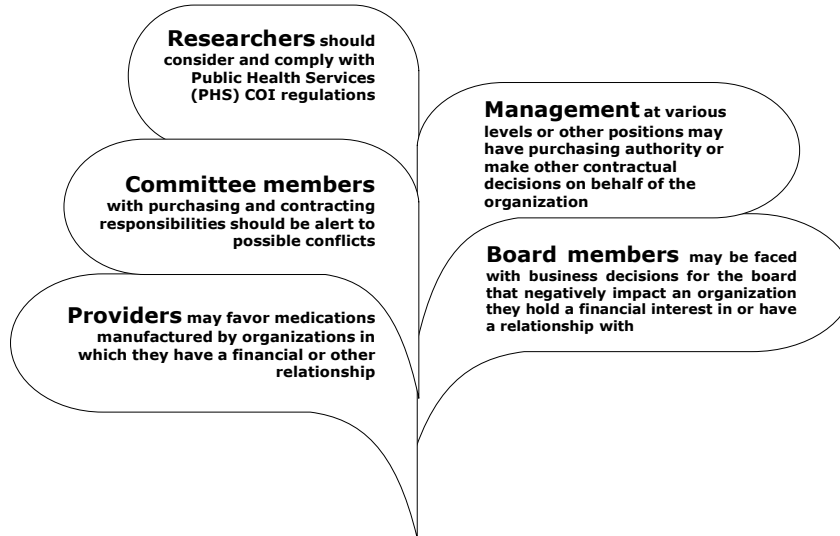
19. <https://ethics.ncsbe.gov/library/pdfs/se/2019%20SEI%20Long%20Form.pdf>

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What's trending | Types of COI implications

Conflicts of Interests impact organizations of many types, including those in which research is not a business activity. There are several ways organizations are at risk of COI violations throughout many levels and areas within the organizations.



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Regulatory and ethical obligations

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What's trending | COI regulations impacting health systems

These regulations are for client consideration and each client should determine what policies are relevant to COI and their COI programs.

PHS regulations

- **42 CFR Part 50, Subpart F** | Requires disclosure of significant financial interested related to research ²⁰
- **45 CFR Part 94** | Applicable to institutions with PHS agreed contracts ²¹

FDA regulations

- **21 CFR Part 54** | Requires disclosure of certain financial interests of investor or investigator family ²²

Sunshine Act

- **Affordable Care Act – Section 6002** | Provides guidance to disclosure requirements to increase financial transparency between physicians, health systems, manufactures and other health care organizations ²³

Internal Revenue Services (IRS)

- **Non-Profit Corporations - 501(c)(3)** | Organization should consider not be operated for benefit of private interests ²⁴
- **Non-profit board disclosures - Form 990** | Requires organizations to report employees compensated above a threshold ²⁵

State Ethics Laws

- **State Ethics Laws** | Many states are governed by their State Ethics Commission to encourage ethics in government activities ²⁶

Other guidance

- **Association of American Medical Colleges (AAMC)** | Offers the "Forum on COI in Academe" which may be joined upon request ²⁷
- **Office for Human Research Protection** | Guidance to determine if COI affects the rights or wellness or human subjects ²⁸
- **AdvaMed Code of Ethics** | Guidance for medical device and diagnostic product companies ²⁹

20. <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d8rgr=div5&view=text&node=42.1.0.1.4.23&idno=42.8ap42.1.50.f>
21. <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d8rgr=div5&view=text&node=45.1.0.1.1.51&idno=45>
22. <https://www.accessdata.fda.gov/scripts/cdrh/cdohs/cfcr/CFRSearch.cfm?CFRPart=54>
23. <https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf>
24. <https://www.irs.gov/charities-non-profits/charitable-organizations/exemption-requirements-501-c-3-organizations>

25. <https://www.irs.gov/pub/irs-pdff/990.pdf>
26. <http://www.ncsl.org/research/ethics/50-state-chart-state-ethics-commissions-jurisdic.aspx>
27. <https://www.aamc.org/professional-development/ethics-groups/foa>
28. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html>
29. <https://www.adva-med.org/issues/code-ethics/code-ethics>

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What's trending | Regulatory updates

In July 2019, the Centers for Medicare and Medicaid Services proposed expanded disclosure requirements for the Open Payments Program – or the Sunshine Act – resulting in three changes.

In addition to those currently identified as "covered recipients," **the definition of covered recipients should be expanded** to include mid-level practitioners (e.g., physician assistants, nurse practitioners, clinical nurse specialists, registered nurse anesthetists, and certified nurse midwives) effective January 1, 2022.

The Nature of Payment Categories should be modified to consolidate accredited/certified and unaccredited/non-certified continuing education program to "medical education programs." Further, the recommendation includes three new categories: Debt Forgiveness, Long-Term Medical Supply or Device Loan, and Acquisitions.

Standardize Data on Reported Covered drugs, Devices Biologicals or Medical Supplies through collaboration with the Food and Drug Administration to establish and implement the inclusion of unique device identifiers (UDIs) on the labels of devices distributed in the US.³⁰

30. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index>

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What's trending | Institutional responsibilities

Healthcare organization's should consider maintaining compliance with state and Federal regulation to promote transparency and protect the objectivity of research.

- **Maintain an up-to-date, written, enforced, and publicly-available policy on Financial Conflict of Interest (FCOI)** that complies with 42 CFR 50 Subpart F
- **Inform Investigators of the Institution's policy on FCOI** and their responsibilities regarding these regulations
- **Require training** prior to engaging in PHS-funded grant, **at least every four years**, and if: (1) there are institutional policy changes, (2) an investigator is a new employee, or (3) an investigator is non-compliant
- If a subrecipient is used, the institution will take reasonable steps to **determine that the subrecipient complies with 42 CFR 50 Subpart F**
- Designate an institutional official to **solicit and review disclosures** of SFI
- Require Investigators participating in PHS grants to submit **SFIs no later than time of application** for PHS-funded research, update disclosures annually, **update SFIs within 30 days** of discovering or acquiring new interests
- Provide **guidelines consistent with 42 CFR 50 Subpart F** for the designated institutional official
- Take actions as required to **manage FCOI**
- Provide initial and ongoing **FCOI reports** to PHS as required
- Establish **enforcement mechanisms** to determine investigator compliance
- **Certify** the institution's administrative processes; enforcement of investigator compliance; FCOI management and reporting, availability of information, and compliance with 42 CFR 50 Subpart F

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What's trending | Foreign support

Healthcare organization across the country are feeling the impacts of increased attention on inappropriate relationships of executives and board members, the need for proper disclosure of conflicts of interest, and transparency of identified conflicts.

Problem Statement

Research organizations are under constant threat by risks to the security of intellectual property and integrity of peer review as some foreign governments have initiated systematic programs to unduly influence and capitalize on U.S.-conducted research.

- Undisclosed foreign financial conflicts: Failure of some NIH-funded researchers to "disclose substantial contributions of resources from other organizations, including foreign governments which threatens to distort decisions about the appropriate use of NIH funds
- Undisclosed conflicts of commitment: Diversion of intellectual property in grant applications or produced by NIH-supported biomedical research to other entities, including other countries
- Peer review violations: Peer reviewers have shared confidential information with others, "including in some instances with foreign entities, or otherwise attempting to influence funding decisions."³¹

Foreign Support

NIH spends more than \$20 billion annually to fund research projects at American institutions.

- Findings indicate numerous NIH-funded researchers at these institutions were publishing papers that listed a foreign institution as their "primary affiliation and cited foreign funding sources in the fine print." These affiliations had not been disclosed to the NIH or their employing institution
- Since August 2018, approximately 180 letters have been sent by the NIH regarding individual scientists whom allegedly failed to disclose sources of research funding
- American Healthcare employees are double accounting for time (i.e., a researcher has funding for 8 months of their time but have other commitments totaling more than 12 months annually)
- Universities are having to refund money to the NIH for salaries paid during times^{32, 33}

31. https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences.pdf?_cldee=YXJyYmVudHNAoXRzeXNOZWoZWR1&recipientid=contact-7c3c47d96887e7118113c15b4286c00_4082380c7b8542c0aad3e89a7a398042&esid=b01f4f69-aaff-e811-a974-000d3a18c23c

32. https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences_report.pdf

33. <https://www.sciencemag.org/news/2019/06/nih-probe-foreign-ties-has-led-undisclosed-firings-and-refunds-institutions>

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Standard practices & improvements

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What's trending | Sources of information

Assessing individuals and institutions for potential conflicts of interest is a complex process requiring several sources of information for a thorough review. Below are sources of information that should be considered during a COI assessment.

#	Data source	Internal / External	Description
1.	Grants & contracts database	Internal	Used to track federal and non-federal grants and contracts
2.	IRB database	Internal	Resource showing the various research studies that involve human subjects
3.	Disclosure data	Internal	Disclosures platform used to organize outside activities
4.	Intellectual Property (IP) storage	Internal	Resource that stores IP owned by the hospital
5.	Physician / third-party contracts	Internal	List of physician contracts with external organizations
6.	Purchasing / supply chain information / accounts payable	Internal	Purchasing history, vendor contracts, purchasing decision makers
7.	Gifts & non-monetary compensation database	Internal	Resource to track gifts made to the hospital
8.	CMS Open Payments Database (<i>Sunshine Act</i>) ³⁴	External	Resource showing payments to physicians from medical device and drug organizations
9.	PubMed ³⁵	External	Resource to search biomedical literature

³⁴. <https://openpaymentsdata.cms.gov/search/physicians/by-name-and-location>







³⁵. <https://www.ncbi.nlm.nih.gov/pubmed/>

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What's Trending | COI program assessment areas

COI Programs may have common pain points leading to inefficiencies in the collection of information to conduct a COI review, the review of the provided information and the management of financial conflicts of interest (FCOI).

 Disclosure Review and Management <ul style="list-style-type: none">• COI programs may be inconsistent in review criteria, review prioritization and conflict management	 Technology <ul style="list-style-type: none">• Current technology is likely not equipped to facilitate efficient data collection
 COI governance structure <ul style="list-style-type: none">• COI governance structure may lack clearly defined reporting channels, roles, and responsibilities	 Staffing and resources <ul style="list-style-type: none">• COI programs may be understaffed for required workload manual process inefficiencies
 Policies and procedures <ul style="list-style-type: none">• Documentation may not be structured to facilitate ease of use and comprehension	 Training and communication <ul style="list-style-type: none">• Inconsistent disclosure channels likely create a lack of transparency for conflicts of interest

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What's trending | New standardized practices

As a result of increased COI scrutiny, healthcare organization compliance offices are evaluating the effectiveness of the established thresholds and the processes to collect information, the review of the information and the management of FCOIs

1. Technology

- Transition from paper to digital disclosure records
- Customization and enhancement of current systems through standardized templates or automated reminders

2. Process

- Separation of anticipated vs. actual income disclosures
- Standardization of review criteria / prioritization
- Integration of review process for project continuations and the reviews of grants / awards with associated protocols
- Customization of management particular to each conflict

3. People

- Participation of physician / clinical leadership in the review of complex cases
- Collaboration with Human Resources to identify covered persons

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What's trending | Questions

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APPENDIX

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Appendix | Proposed changes

(1) Expanding the definition of a covered recipient

Section 1128G of the Act requires applicable manufacturers and applicable GPOs to report annually information about certain payments or other transfers of value made to covered recipients, as well as ownership or investment interests held by physicians or their immediate family members in such entities, though at section 1128G(e)(7) of the Act it exempts physicians who are employed by the reporting manufacturer, such that manufacturers do not report payments to their own employees. As we noted previously, section 6111 of the SUPPORT Act expanded the definition of covered recipients from physicians and teaching hospitals to include PAs, NPs, CNSs, CRNAs, and CNMs; it likewise expanded to these individuals the same exception for manufacturer-employment.

The SUPPORT Act requires these changes to be in effect for information required to be submitted on or after January 1, 2022. In short, applicable manufacturers will be required to report transfers of value pertaining to these additional provider types in the same way they have been required to report transfers of value to physicians and teaching hospitals. Since the information is reported to CMS in the calendar year following the year in which it was collected, this means that the data would be collected by the industry during CY 2021. We are proposing to revise § 403.902 to align with the statutory requirements in sections 1128G(e)(6)(A) and (B) of the Act.

Specifically, we are proposing to revise the definition of “covered recipient” in § 403.902 to include PAs, NPs, CNSs, CRNAs, and CNMs. In addition, we are proposing at § 403.902 to reference the definitions of these additional provider types as defined in sections 1861(aa)(5)(A), 1861(aa)(5)(B), 1861(bb)(2), and 1861(gg)(2) of the Act. We are also proposing to update certain provisions in part 403, subpart I to include provider and supplier types other than physicians as specified in sections 1128G(e)(6)(A) and (B) of the Act.

Specifically, we propose the following revisions:

- In § 403.902, to add the definitions of “certified nurse midwife,” “certified registered nurse anesthetist,” “clinical nurse specialist,” “non-teaching hospital covered recipient,” “nurse practitioner,” and “physician assistant.”
- In § 403.902, to revise the definition of “covered recipient” by adding physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife” after the phrase “Any physician.”
- In § 403.904(c)(1), (f)(1)(i)(A), and (h)(7), to replace the term “physician” with the phrase “non-teaching hospital.”
- In § 403.904(c)(3), to replace the term “physician” in the title with the phrase “non-teaching hospital,” add the phrase “non-teaching hospital” after “In the case of a,” and remove the phrase “who is a physician” from the text.
- In § 403.904(c)(3)(ii) and (iii), (f)(1)(i)(A)(1), (f)(1)(i)(A)(3) and (5), and (f)(1)(v), to change the term “physician” to the phrase “non-teaching hospital covered recipient.”
- In § 403.904(h)(13), to remove the phrase “who is a physician” and add the phrase “non-teaching hospital” after “In the case of.”
- In § 403.904(f)(1), to remove the phrase “(either physicians or teaching hospitals).”
- In § 403.908(g)(2)(ii), to change the words “physicians and teaching hospitals” to the term “Covered recipients.”

30. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index>

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Appendix | Proposed changes continued

(2) Nature of Payment Categories

Applicable manufacturers and applicable GPOs must characterize the nature of payments made to covered recipients by selecting the "Nature of Payment" category that most closely describes the reported payment. Some of the "Nature of Payment" categories, as specified at § 403.904(e)(2), are specifically required by section 1128G(a)(1)(A)(vi) of the Act, while the statute also allows the Secretary to define any other nature of payment or other transfer of value. Based upon information we obtained from the public comments solicited in the CY 2017 PFS proposed rule (81 FR 46395), stakeholders have identified debt forgiveness, long term medical supply or device loan, and acquisitions (among others) as useful categories to add to comply with the general reporting requirement under section 1128G(a)(1)(A) of the Act. Therefore, and so as to add clarity to the types of payments or transfers of value made by applicable manufacturers and applicable GPOs to covered recipients, we are proposing to revise the "Nature of Payment" categories in § 403.904(e)(2) by consolidating two duplicative categories and by adding the three new categories described below.

First, the categories that we are proposing to consolidate include two separate categories for continuing education programs. Section 1128G(a)(1)(A)(vi)(XIII) of the Act requires manufacturers to report direct compensation for serving as faculty or a speaker for medical education programs. The current § 403.904(e)(2)(xiv) and (xv) distinguish between accredited/certified and unaccredited/non-certified continuing education programs. At proposed revised § 403.904(e)(2)(xv), we are proposing to consolidate these categories and make the regulatory wording match the statutory language "medical education programs," which we believe would streamline the reporting requirements while not detracting from the underlying context of the data. Although we defined separate categories at the inception of the Open Payments program, we no longer believe that the distinction in this category is necessary. In addition, we are proposing three additional categories that would operate prospectively and would not require the updating of previously reported payments or other transfers of value that may fall within these new categories.

The three new categories are as follows:

- Debt Forgiveness (proposed § 403.904(e)(2)(xi)): This would be used to categorize transfers of value related to forgiving the debt of a covered recipient, a physician owner, or the immediate family of the physician who holds an ownership or investment interest.
- Long-Term Medical Supply or Device Loan (proposed new § 403.904(e)(2)(xiv)): Section 403.904 currently contains an exclusion from reporting for the loan of a covered device, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days, or a quantity of 90 days of average use, respectively. This new category would be used to characterize the loans of covered devices or medical supplies for longer than 90 days. (Note: We are proposing to combine current paragraphs on continuing education programs § 403.904(e)(2)(xiv) and (xv) to replace paragraph (e)(2)(xv) as noted in the consolidating continuing education programs above.)
- Acquisitions (proposed § 403.904(e)(2)(xviii)): This addition would provide a category for characterizing buyout payments made to covered recipients in relation to the acquisition of a company in which the covered recipient has an ownership interest. We also are proposing to add the definition of "long-term medical supply or device loan" to § 403.902 as "the loan of supplies or a device for 91 days or longer." For consistency within the definitions section, we propose to redesignate § 403.904(h)(5) - which contains the definition of "short-term medical supply or device loan" to § 403.902. As a result, we are proposing a new § 403.904(h)(5) to be "short-term medical supply or device loan."

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30. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index>

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Appendix | Proposed Changes Continued

(3) Standardizing Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies

When applicable manufacturers or applicable GPOs report payments or transfers of value related to specific drugs and biologicals, we currently require names and NDCs to be reported to the Open Payments program. However, based upon the lack of federally-recognized identifiers when we started the Open Payments program, we have not required analogous reporting for medical devices from the manufacturers. However, the Food and Drug Administration (FDA) established and continues to implement a system for the use of standardized unique device identifiers (UDIs) for medical devices and has issued regulations at 21 CFR part 801, subpart B, and 21 CFR part 830, requiring, among other things, that a UDI be included on the label of most devices distributed in the United States. (See 78 FR 58785, September 24, 2013.)

Based upon the FDA's UDI regulatory requirements and the HHS Office of the National Coordinator's requirement that UDIs form part of the Common Clinical Data Set (45 CFR part 170), we believe that the use of UDIs and device identifiers (DIs), a subcomponent of the UDI, have become more standardized. Moreover, the HHS Office of Inspector General (OIG) included a recommendation for Open Payments to require more specific information about devices in an August 2018 report (OEI-03-15-00220).

With the standardization and typical use of UDIs and based upon OIG's recommendation, we propose that the DI component, the mandatory fixed portion of the UDI assigned to a device, if any, should be incorporated into Open Payments reporting that applicable manufacturers or applicable GPOs provide. We do not propose to require a full UDI. We believe such a step would substantially aid in enhancing the quality of the Open Payments data because the identifiers can be used to validate submitted device information. This effort would also enhance the usefulness of Open Payments data to the public by providing more precise information about the medical supplies and devices associated with a transaction. Specifically, we are proposing to revise § 403.904(c)(8) to require applicable manufacturers and applicable GPOs to provide the DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly.

We also seek to further clarify the reporting requirements with regard to drugs and biologicals. Since the outset of the Open Payments program, NDCs have been required for both research and non-research payments. In § 403.904(f)(1)(iv), we require that NDCs be reported for drugs and biologicals used in research. However, in the CY 2015 PFS final rule with comment period (79 FR 67548), the non-research payment NDC requirement was erroneously removed when changes were made to the rule text regarding marketed names. We propose to correct this error in order to reiterate that NDCs are required for both research and non-research payments and to make the change effective 60 days from publishing the final rule. We propose to revise § 403.904(c)(8) to require DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly. We also propose to reincorporate language that specifically requires reporting of NDCs. As a result of the proposed changes to § 403.904(c)(8), we are also proposing technical changes to § 403.904(f)(1)(iv) and to add mirrored definitions from 21 CFR 801.3 for "device identifier" and "unique device identifier" to § 403.902.

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30. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index>

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COI SOURCES OF INFORMATION



COI REGULATIONS IMPACTING HEALTH SYSTEMS

These regulations are for client consideration and each client should determine what policies are relevant to COI and their COI programs.

PHS regulations

- **42 CFR Part 50, Subpart F** | Requires disclosure of significant financial interested related to research
- **45 CFR Part 94** | Applicable to institutions with PHS agreed contracts

FDA regulations

- **21 CFR Part 54** | Requires disclosure of certain financial interests of investor or investigator family

Sunshine Act

- Affordable Care Act – Section 6002

IRS

- Non-Profit Corporations - 501(c)(3)– Organization must not be operated for benefit of private interests
- Non-profit board disclosures Form 990

Other guidance

- Association of American Medical Colleges (AAMC)
- Office for Human Research Protection guidance
- AdvaMed Code of Ethics – Medical device and diagnostic product companies

COI SOURCES OF INFORMATION

The following sources of information should be considered when assessing potential COIs:

#	Data source	Internal / External	Description	Why needed?
1	Grants & contracts database	Internal	Used to track federal and non-federal grants and contracts	Review PHS grants for the timely distribution of funds
2	IRB database	Internal	Resource showing the various research studies that involve human subjects	Identify research studies requiring COI evaluation
3	Disclosure data	Internal	Disclosures platform used to organize outside activities	Evaluate financial interests for potential conflicts
4	Intellectual Property (IP) storage	Internal	Resource that stores IP owned by the hospital	Cross reference IP ownership to disclosed information
5	Physician / third-party contracts	Internal	List of physician contracts with external organizations	Evaluate if physician's contracts conflict with current research
6	Purchasing / supply chain information / accounts payable	Internal	Purchasing history, vendor contracts, purchasing decision makers	Mitigate conflicts in purchasing decisions and review vendor relationships
7	Gifts & non-monetary compensation database	Internal	Resource to track gifts made to the hospital	Identify if gifts from external sources could impact decisions
8	CMS Open Payments Database (<i>Sunshine Act</i>)	External	Resource showing payments to physicians from medical device and drug organizations	Providers external source for monitoring and auditing activities
9	PubMed	External	Resource to search biomedical literature	Evaluate if physician COIs are reported in research publications

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