

**PCPI Webinar**  
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**Legal Issues in  
Quality Measure Development  
and Sharing**

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# Road Map

- IP 101
- Background on Ownership of Registry Data/Measures
- Legal/Contractual Issues
- Regulatory Issues

# IP 101

- IP rights fall into several categories
  - Copyright
  - Trademark/Service Mark
  - Patent
  - Trade Secrets

# IP 101

- IP rights fall into several categories
  - Copyright
    - Protected by federal copyright law and common law
    - Original works of authorship fixed in any tangible medium of expression
    - Includes compilations and arrangements of data that are “selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship”
    - So, registry databases, data fields, data elements, data dictionaries and quality measures may all be protected by copyright
    - Registration of copyright with the federal Copyright Office can provide additional protection, but not practical for most registry IP, except measures
    - © [name of registry] [year]. All rights reserved.

# IP 101

- Copyright

- Derivative Works—“a work based upon one or more preexisting works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgment, condensation, or any other form in which a work may be recast, transformed, or adapted. A work consisting of editorial revisions, annotations, elaborations, or other modifications which, as a whole, represent an original work of authorship, is a ‘derivative work.’”
- Fair Use Exception
  - Applies to limited use of copyrighted work for certain allowed purposes—e.g., criticism, comment, news reporting, teaching, scholarship, or research

# IP 101

- IP rights fall into several categories
  - Patent
    - Federal patent law protects first use of novel inventions, including processes or methods
    - No common law equivalent
    - Patent law precludes others from using or selling the patented process or method without permission of the patent holder for 20 years
    - Some registry technology or algorithms may be patentable, but patent application and review process is very time consuming and expensive

# IP 101

- IP rights fall into several categories
  - Trademark/Service Mark
    - Federal trademark law and common law protect trademarks and service marks
    - Trademarks protect brand names, usually for products
    - Service marks are a type of trademark that protect names, logos, and tag lines or slogans
    - Registry name, logo, and tag lines can and should be registered with the US Patent and Trademark Office
    - ® vs. TM vs. SM

# IP 101

- IP rights fall into several categories
  - Trade Secrets
    - No formal federal statutory protection
    - Uniform Trade Secrets Act has been adopted by most states
    - "**Trade secret**" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
    - Registry technology, algorithms, etc. may be protected trade secrets

# Ownership of Registry Data

- Database participation agreement defines the applicable terms of participation
- Database participation and vendor agreements should clarify ownership of data
  - Distinguish between raw data and the database
  - Typically sites will retain ownership of raw data they submit
  - Database owner will own:
    - The database (including the aggregate data and subsets of data, data fields/elements, etc.)
    - Any reports/analysis based on the data
    - Information derived from the data
    - All trademarks, trade secrets, and intellectual property arising from or reflected in the database
  - Patients have interest in data but generally not ownership
  - Check state law--<http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison>

# Ownership of Quality Measures

- Quality measures are subject to copyright protection if:
  - They constitute original works or authorship
  - So must be original
  - Must be an expression of ideas or concepts
  - Must be fixed in a tangible medium—e.g., recorded in a written form
- Copyrightable works include compilations and arrangements of data that are “selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship”
  - Most measures would fit this definition
  - Similar to AMA CPT Code, but even stronger case for copyright protection because of analytical basis for measures

# Ownership of Quality Measures

- Derivative Works
  - A derivative work is a work based on or derived from one or more existing works.
  - Common derivative works include
    - Translations
    - Musical arrangements
    - Motion picture versions of literary material or plays
    - Art reproductions
    - Abridgments and condensations of preexisting works
    - “New edition” of a preexisting work in which the editorial revisions, annotations, elaborations, or other modifications represent, as a whole, an original work
  - To be copyrightable, a derivative work must incorporate some or all of a preexisting “work” and add new original copyrightable authorship to that work

# Ownership of Quality Measures

- Note that anyone who works on measure development will have an ownership interest
  - So, all volunteers and others working on measure development committees must be required to assign (in writing) their copyright interest in measures to society or other organization that will own the measure
  - Assignment agreements should also cover confidentiality and conflict of interest

# Licensing of Quality Measures

- Entities that wish to use another entity's measure or develop a new measure based on an existing measure (i.e., a **derivative work**) must have permission (i.e., a **license**) from the original owner (i.e., the **licensor**)
  - This is required by copyright law
  - Consistent with CMS rules for using another entity's QCDR measures
- License Agreements
  - Grant of license with conditions, including approval of all uses or changes
  - Royalty?
  - Indemnifications
  - Other standard contract terms

# Ownership vs Stewardship

- Ownership is a property right determined by state and federal law
  - Ownership of measures is primarily determined by federal and state intellectual property
  - Underlying data is owned by data sources, but measures are owned by entity that puts in the work to develop them
- Stewardship is a fiduciary concept relating to a caretaker role
  - Arises frequently in privacy context
  - An entity can be the measure steward without having ownership

# COI Policies for Quality Measures

- Question is whether COI policies for clinical guidelines should apply to quality measures
- Both share need for members of guidelines/measure committee to be objective and unbiased
- Public perceptions are critical to ensure integrity of process
- All policies require disclosure of conflicts, but differ in scope of disclosure and level of permissible conflict

# COI Policies for Quality Measures

- *IOM Standards for Developing Trustworthy Clinical Practice Guidelines, March 2011*
  - Whenever possible, guidelines group members should not have conflicts; but no more than a minority of the group should have conflicts
- NQF COI Policy for Measure Endorsement Committee Members
  - Full disclosure required
  - Must recuse themselves from discussion and voting regarding any measure for which they have a conflict of interest
  - <https://www.qualityforum.org/nominations/>

# COI Policies for Quality Measures

- CMSS Code for Interactions:
  - Societies will determine whether the term Clinical Practice Guidelines applies to clinical performance measures and safety standards developed by the Society.
  - No Company support allowed
  - Full disclosure required
  - Chair of quality measure committees may not have conflicts and a majority of committee members would need to be without conflicts as well
  - <https://cmss.org/code-signers-pdf/>

# COI Policies for Quality Measures

- CMS Blueprint for Measure Management Systems
  - “All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members’ perspectives and how that might affect discussions or recommendations.”

# COI Policies for Quality Measures

- CMS Blueprint for Measure Management Systems (cont.)
  - “Best efforts will be made so that TEP members will not have a material interest as defined in this Conflict of Interest Policy. In the exceptional situation in which avoidance of Technical Expert Panel members with a material interest is extremely difficult because of the critical need for their expertise, PCPI will...[ensure that]...no more than 25% of the total TEP can have a material interest”
  - <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf>

# COI Policies for Quality Measures

- PCPI Policy
  - Determination of a material interest is based on whether or not the activity of the individual may be reasonably expected to impact the activities or decisions of the technical expert panel

# QCDR Quality Measures

- CMS considers MIPS measures to be in public domain
  - No legal justification for this position
- Treats QCDR measures differently
  - Current policy: any QCDR seeking to use another QCDR's measures in MIPS program must obtain approval from measure owner and cite such permission in self-nomination application
    - "If a QCDR would like report on an existing QCDR measure that is owned by another QCDR, they must have permission from the QCDR that owns the measure that they can use the measure for the performance period." CY 2018 QPP Final Rule

# QCDR Quality Measures

- In 2019 PPFS, CMS proposed to change its policy and require all QCDR's to license their measures to CMS, allowing CMS to make the measures freely available to other QCDRs.
- CMS backed off in final rule after registry community objected very loudly
- CMS still concerned about availability of QCDR measures to non-owner QCDRs

# QCDR Quality Measures

- Ownership vs Stewardship
  - CMS has not formally distinguished between these different legal concepts for QCDR measures
  - But agency officials have expressed openness to allowing QCDRs to serve as measure steward for purposes of MIPS reporting without being measure owner as long as they have permission from owner to do so
    - CMS officials have indicated that they would likely ask for documentation indicating that measure stewardship has been transferred to the measure steward from the measure owner

# QCDR Quality Measures

- QCDR Measures that are Derivative Works
  - Per definition, must be based on an existing measure
  - To be separately copyrightable, the derived measure must include additional copyrightable material
  - Whether a quality measure is a derivative work is going to depend on the facts and circumstances

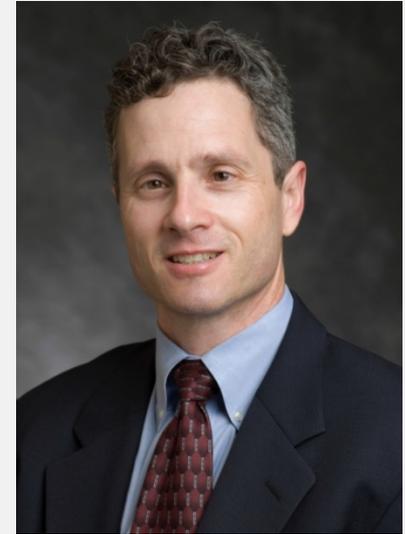
# QCDR Quality Measures

- Licensing vs Harmonization
  - CMS struggling to distinguish between QCDR measures that need to be licensed vs those that should be harmonized
  - Those that make minor changes to an existing measure or that are essentially derivative works should be subject to licensure from existing measure owner
  - Those that are materially different and not a derivative work of another measure should be subject to harmonization (if appropriate)
  - CMS needs to clarify when it will require harmonization vs. licensing

QUESTIONS?

# Robert M. Portman

Robert M. Portman is a principal in the law firm of Powers Pyles Sutter and Verville PC in Washington, DC. Mr. Portman concentrates his practice in health and association law, focusing on legislation and regulation in the health care field, patient privacy, governance, tax exemption, transactions, certification law, administrative law, antitrust, and election and lobbying law. He represents a wide range of non-profit health care organizations including a large number of national professional societies, trade associations, other health care associations, voluntary health organizations and certification bodies, as well as numerous clinical data registries and the Physician Clinical Data Registry Coalition. Mr. Portman graduated *magna cum laude* from Harvard Law School and holds a masters in public policy from the Harvard Kennedy School of Government. He graduated *summa cum laude* from Northwestern University with a BA in Economics.



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