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IRMS 33rd Annual Risk Managers' Meeting:

Maximizing Your State and Federal Peer Review Protections in a Clinically Integrated Provider Network

October 5, 2017 | 9:45 a.m.

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Hypothetical

- You get a call from the Health System CMO, Dr. Susan Carealot, who also Chairs the Health System's ACO/CIN Quality and Credentials Committee. She informs the RM and GC, that the ACO/CIN's administrative offices have received a subpoena from a medical malpractice attorney for all ACO/CIN and Health System records and documents pertaining to the ACO/CIN's review of care provided to a Ms. Hada Bad-Outcome. Ms. Hada Bad-Outcome's family is suing the providers involved in her care for malpractice and negligent credentialing. All of her providers are ACO participants, including a PCP employed by Health System Physician Group, a cardiac surgeon who is a member of a participating independent physician group, a Health System hospital, and an affiliated skilled nursing facility.

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Hypothetical

- Dr. Carealot tells you that Ms. Hada Bad-Outcome is a 65 year old CEO of a large, closely –held family company, who has 4 minor children and a stay-at-home husband, who experienced severe complications after her hypertension went undiagnosed by a Health System PCP. Ms. Bad-Outcome had seen the PCP because she was experiencing severe headaches, anxiety and nosebleeds. He believed she was stressed and dehydrated from travel, and prescribed zoloft and regular exercise. Two weeks later she experienced a heart attack, and after a CABG procedure performed by the independent surgeon, developed post-surgical complications, and had a stroke. During her subsequent rehabilitation at a SNF, a medication error caused her to have another stroke, and she is now in a vegetative state.

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Hypothetical

- Dr. Carealot provides you copies of the applicable peer review policies for the health system, and the credentialing and quality review procedures of the ACO/CIN, and asks you to analyze whether the medical records and peer review materials reviewed and produced by the ACO/CIN are privileged from discovery. She does not want to release the records because after reviewing the case, the ACO/CIN's Quality and Credentials Committee determined that the PCP, who had a history of noncompliance with care protocols and poor quality scores, had not followed standard procedures for assessing the patient for hypertension. She also tells you that the cardiac surgeon had a history of similar post-surgical complications, and that based on this data, they decided he should be terminated from participation in the ACO/CIN.

Factors/Questions to be Assessed

- Are you seeking state and/or federal privilege protections?
- What is the scope of protected activities? -- peer review, quality improvement, RCAs, adverse events.
- What corporate entities, licensed facilities, licensed health care practitioners or others are protected under state/federal laws?
- What committees or organizational construct is required in order to assert the protections?
- Are your existing bylaws, rules, regs and policies properly structured to maximize available privilege protections?
- Can privileged information be shared across the ACO/CIN without waiving the privilege?
- How does applicable case law affect statutory interpretation?
- What impact, if any, of mandated adverse event reporting obligations?
- Never events, hospital acquired infection
- Do state privilege protections apply to federal claims filed in federal court, i.e., antitrust, discrimination?

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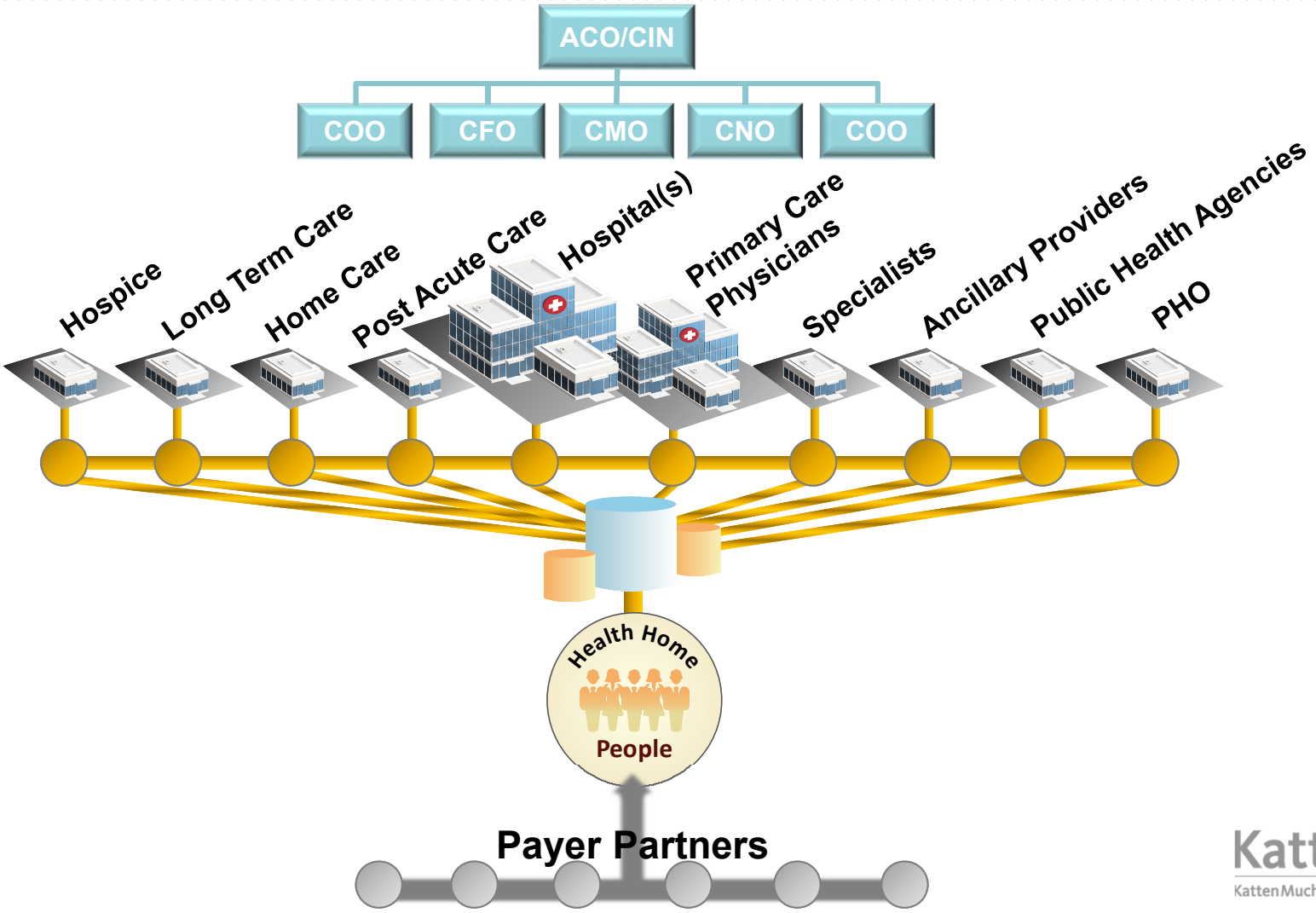
Complete view of an operational ACO/CIN



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Summary and Analysis of Illinois Medical Studies Act

- Medical Studies Act
  - 735 ILCS 5/8-2101
    - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data.
    - Allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities.
    - Their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs.

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Summary and Analysis of Illinois Medical Studies Act

- Including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donations.
- Shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services.
- Information can be used in disciplinary hearings and subsequent judicial review.

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Summary and Analysis of Illinois Medical Studies Act

- Protections have been interpreted fairly broadly but information produced for a different purpose, i.e., risk management, is not protected even if used by a peer review committee.
- Although the Medical Studies Act references "medical organizations" under contract with HMOs or other healthcare delivery entities or facilities, surgicenters and hospitals, Appellate Courts have not extended protections to nursing homes or pharmacies.
- Recent 2nd District Appellate Court decisions have rejected the application of the privilege protections to materials and discussions generated after an event or investigation has been initiated by an identified peer review committee used exclusively for peer review/ quality activities.

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Summary and Analysis of Illinois Medical Studies Act

- Protections cannot be waived if used for statutory purposes.
- Information arguably can be shared throughout the system among controlled affiliates as well as specific physician information if authorized.
- Protections do not apply to federal claims brought in federal court.

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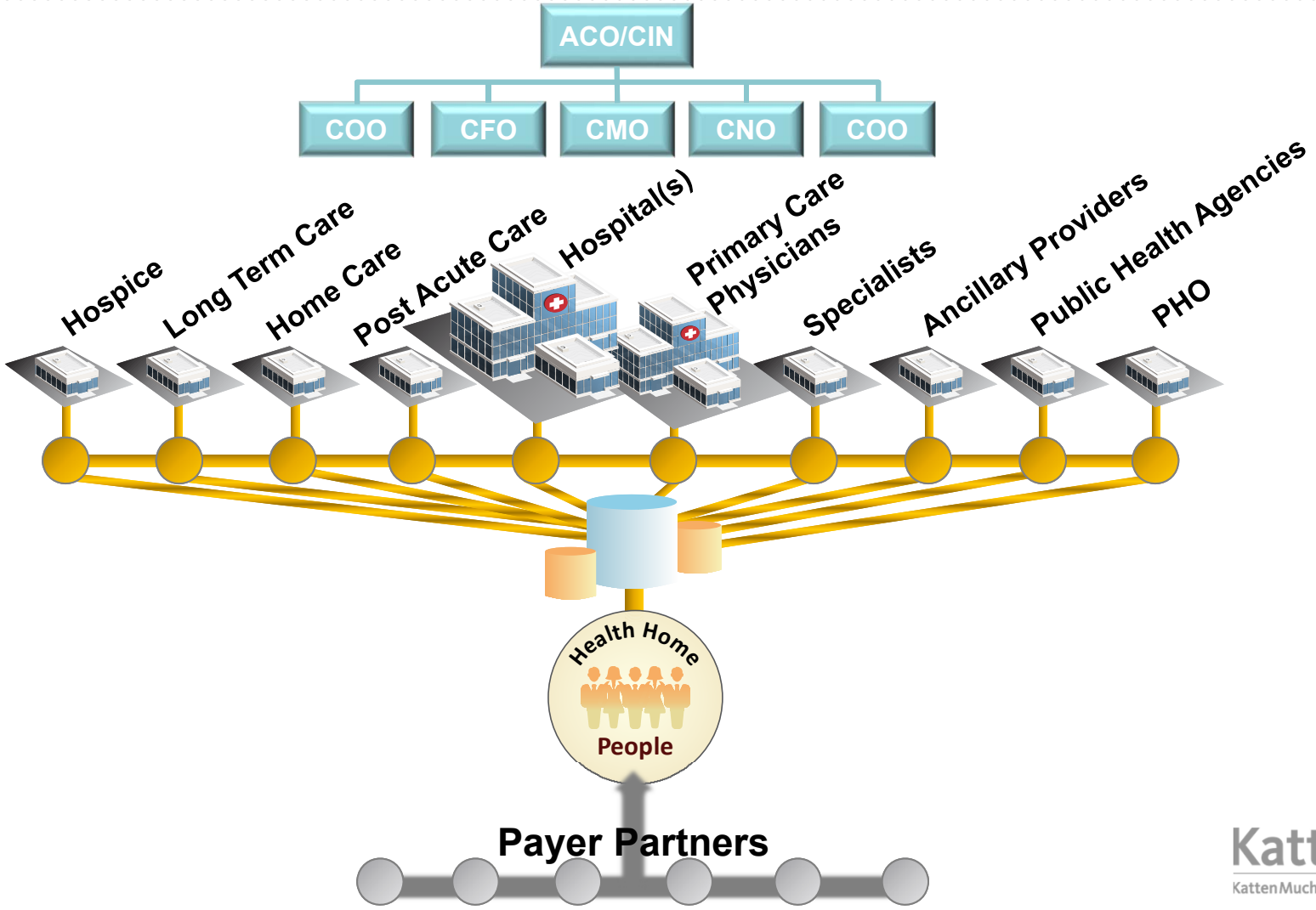
Complete view of an operational ACO/CIN



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Summary and Analysis of Illinois Medical Studies Act

- Analysis
  - Does statute arguably protect requested records?
    - Medical records – No
    - Bylaws, policies and procedures – No
    - Peer review records and entities
    - Does ACO/CIN Quality and Credentials Committee qualify as a peer review committee? – probably, BUT
    - Is ACO/CIN a hospital, surgicenter, HMO, PHO or post-surgical recovery center? - No
    - If physician group is conducting peer review through a medical review committee or through ACO/CIN Quality and Credential Committee are those activities protected? – No
    - What about the SNF? – No
    - What about the PHO? – Probably

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Summary and Analysis of Illinois Medical Studies Act

- Can privileged information be shared across ACO/CIN?
  - Under the hypothetical only peer review/quality information generated by a hospital peer review committee or designee will be privileged.
  - Under the MSA the privilege cannot be waived unless used for activities unrelated to improving patient care or for reducing morbidity or mortality.
  - Privileged information arguably could be shared with the ACO/CIN.
- Does MSA privilege apply in federal proceedings? – No

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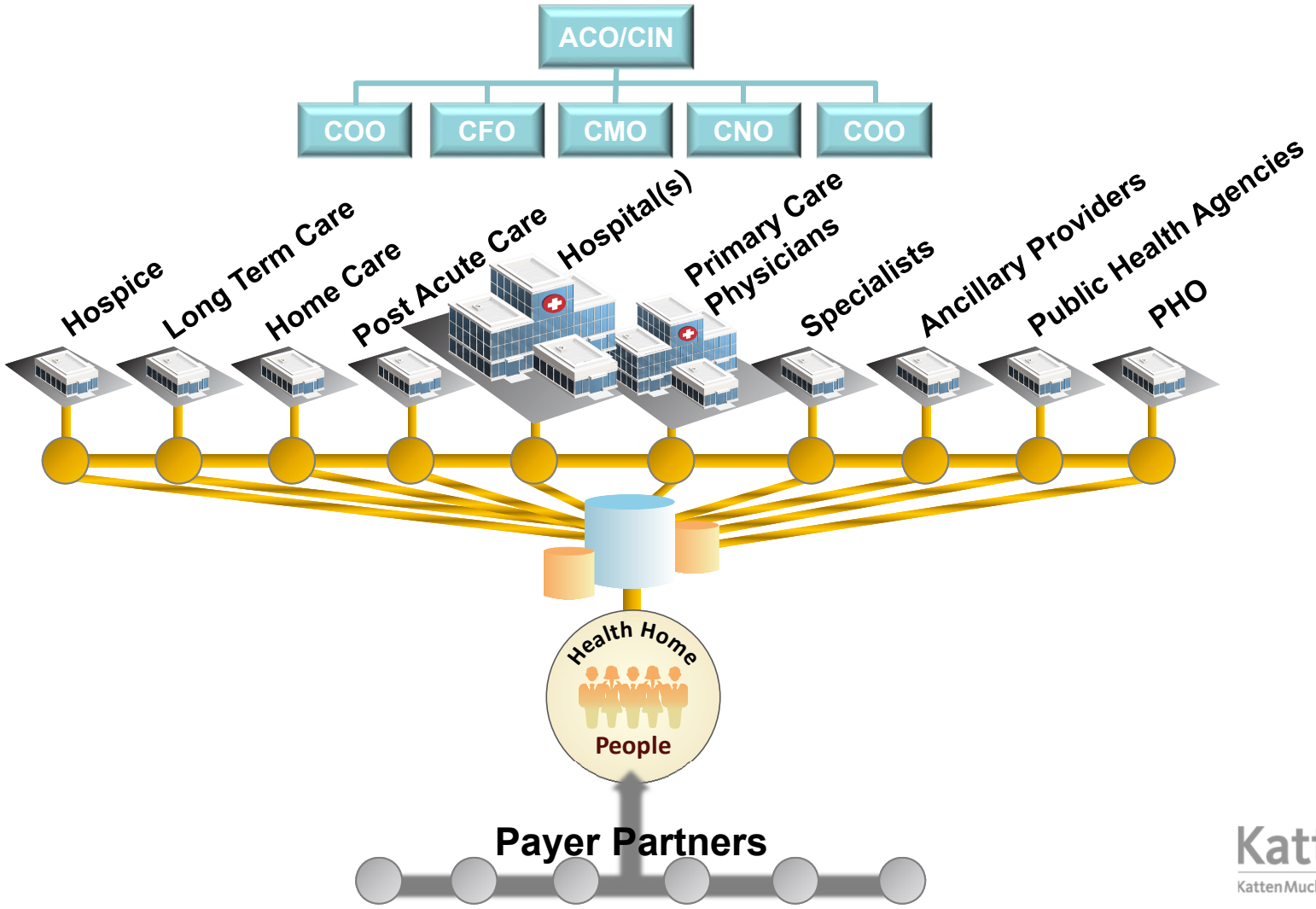
Complete view of an operational ACO/CIN



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Patient Safety and Quality Improvement Act of 2005

- Privileged Patient Safety Work Product
  - Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

  And that:

  - Are assembled or developed by a provider for reporting to a PSO and are reported to a Patient Safety Organization (PSO), which includes information that is documented as within a patient safety evaluation system (PSES) for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
  - Are developed by a PSO for the conduct of patient safety activities; or
  - Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

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Patient Safety Act (cont'd)

- What types of information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality?

  - Medical error or proactive risk assessments, root cause analysis
  - Risk Management – Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
  - Outcome/Quality—may be practitioner specific
  - Peer review
  - Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks
  - Deliberations or analysis

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Patient Safety Act

- What is not PSWP?
  - Patient's medical record, billing and discharge information, or any other original patient or provider information
  - Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP*
  - PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:
    - Information has not yet been reported to a PSO; and
    - Provider documents the act and date of removal of such information from the PSES
  - Reports that are the subject of mandatory state or federal reporting or which may be collected and maintained pursuant to state or federal laws be treated as PSWP
    - Illinois Adverse Health Care Reporting Law of 2005

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Patient Safety Act

- What entities are covered under the Act?

  - All entities or individuals licensed under state law to provide health care services or which the state otherwise permits to provide such services, i.e., hospitals, SNFs, physicians, physician groups, labs, pharmacies, home health agencies, etc.
  - A non-licensed corporate entity that owns, controls, manages or has veto authority over a licensed provider is considered a provider.

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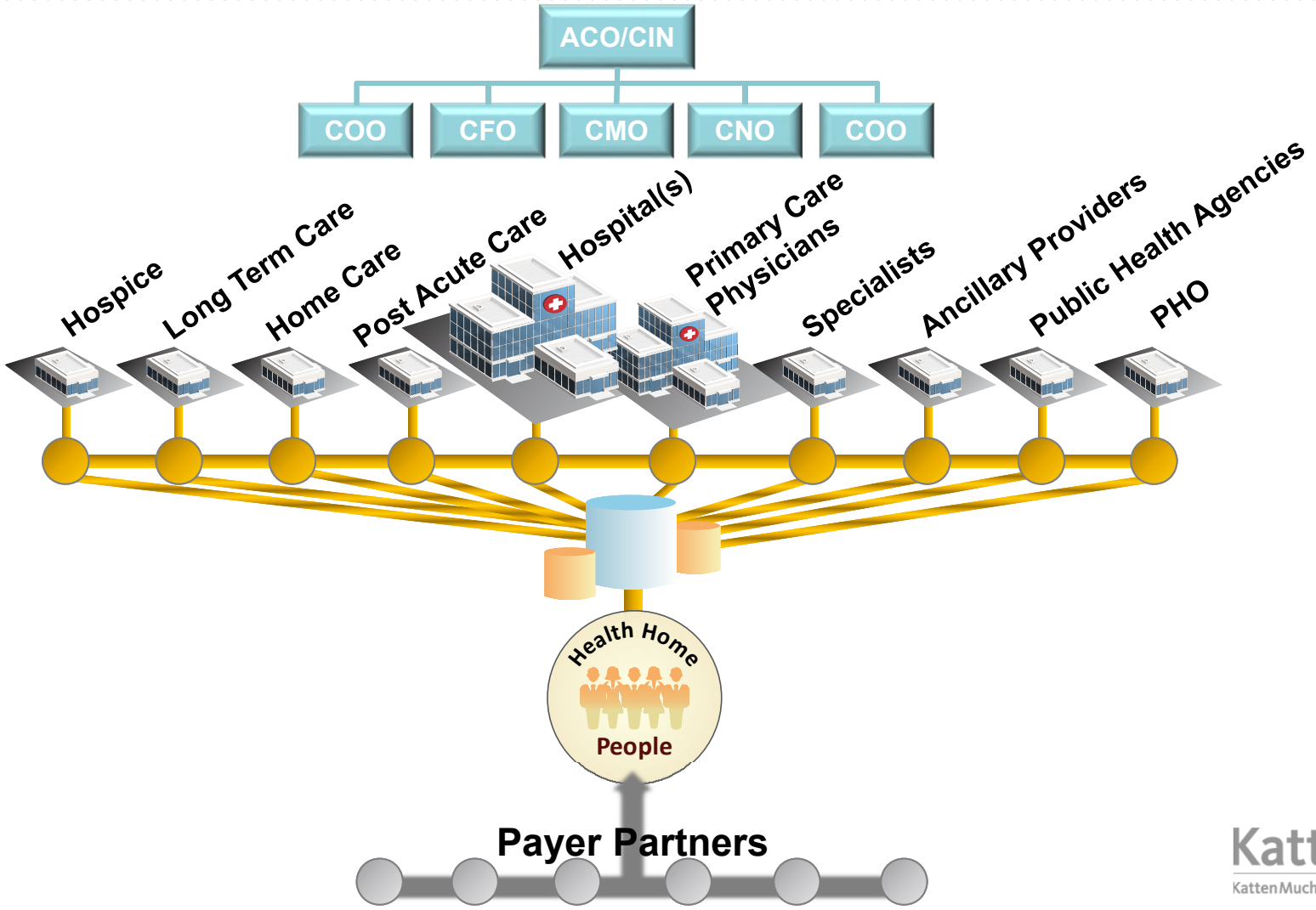
Complete view of an operational ACO/CIN



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Patient Safety Act (cont'd)

- Analysis
  - Do the protections apply to the requested documents?
    - Medical records – No
    - PSES policies and procedures – No
    - Records that must be reported (or collected and maintained) by a state or federal law – No
    - Committee reports, analysis, etc.
      - Yes, if collected and identified in a system-wide PSES or in the PSES of a provider which has collected the PSWP for reporting to a PSO and is reported or if it constitutes deliberation or analysis
  - Are all ACO/CIN entities covered?
    - All licensed providers facilities and the physician are covered if participating in a PSO
    - ACO/CIN is not covered unless it is a licensed provider and/or it owns, controls or manages licensed providers or has veto authority over decision making
    - If not, patient safety and peer review activities must be conducted in a licensed facility.

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Patient Safety Act (cont'd)

- What about the PHO? – No, it is not a licensed provider
- Can PSWP be shared?
  - Identifiable PSWP can be shared by and between affiliated providers
  - Physicians and other licensed professionals need to authorize, in writing, the sharing of identifiable PSWP
- Can protections be waived?
  - There are disclosure exceptions but privilege protections are never waivable
- Do protections apply in all state and federal proceedings?
  - Yes

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Comparison of Medical Studies Act to the Patient Safety Act

- Patient Safety Act
  - The confidentiality and privilege protections afforded under the PSA generally apply to reports, minutes, analyses, data, discussions, recommendations, etc., that relate to patient safety and quality if generated or managed, or analyzed within the PSES and collected for reporting to a PSO.
  - The scope of what patient safety activities can be protected, generally speaking, is broader than the activities and documents privileged under the MSA.
  - The scope of what entities can seek protection is much broader.

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Comparison of Medical Studies Act to the Patient Safety Act

- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived under any circumstances.
- PSA pre-empts state law – IDFPR v. Walgreens.
- Non-provider corporate parent organization involved in patient safety activities as well as owned, controlled or managed provider affiliates can be included in a system-wide PSES and be protected.
- PSWP can be shared among affiliated providers.
- PSWP is not admissible into evidence nor is it subject to discovery.
- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").

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