Establishment and Governance

Presentation to the Health Planning Committee of the Public Health and Health Planning Council
New York State Department of Health
September 19, 2012

Goals for Meeting

- Consider update of C&C reviews of:
  - Complex corporate structures;
  - Not-for-profit boards
- Rationalize the criteria that trigger disqualification from establishment and the parties that are disqualified;
- Consider mechanisms to strengthen governance, especially in light of new systems of care.

CHARACTER
&
COMPETENCE

Character & Competence: Process

- Two steps:
  - Review of qualifications and compliance record of individuals in governing body;
  - Determine whether violations of regulations by affiliated facilities/home care agencies trigger disqualification (“taint”).

Step 1: Review of Individual Qualifications

- Goal: Authorize persons with "the character, experience, competence and standing in the community" to operate health care facilities, home care agencies and hospices.
- Current process for assessment:
  - Character: Applicant provides actions against professional licenses or certificates, criminal proceedings.
  - Competence: Applicant provides employment history, surveillance record, civil and administrative actions, other compliance-related actions.

Character and Competence Reviews

Type	Check Type	Source	Notes
Establishment	Schedule 2A Check	Schedule 2A	Personal History of the natural persons
Establishment	Out of State Compliance Check	Schedule 2D	Other states submit compliance information about facilities operated in their state by the applicant corporation
All	Pending Enforcements	Enforcements Databases	Puts project “on hold” until enforcement is resolved.
Establishment	Taint	Enforcements Databases	Two enforcements for the same transgression taints any individuals serving at the time of both transgressions.
Establishment	Medicaid Exclusion	www.omig.ny.gov	
Establishment	Medicare Exclusion	www.oig.hhs.gov	
Establishment	OPMC Completed Disciplinary Actions	http://www.nyhealth.gov	
Establishment	NYS Education Department Licensure Database	http://www.op.nysed.gov/opsearches.htm	To check status of professional licensure
Establishment	Other License Verification Databases	Varied	To verify licenses granted by other states, and other professions licensed by New York State.
Establishment	Intra-/Inter-Agency Check	OHIP, OPH, OMH, OASAS, OPWDD	

Step 2: "Taint" or Disqualification (PHL 2801-a(3))

- With respect to an individual;
- Within the past ten years;
- Who has been an . . . operator of any hospital or other residential facility;
- "[N]o approval shall be granted unless the [PHHPC] . . . shall affirmatively find by substantial evidence a substantially consistent high level of care is being or was being rendered;"
- No finding of a substantially consistent high level of care where there have been violations that:
  - threatened to directly affect the health, safety or welfare, and
  - were recurrent or were not promptly corrected.

C&C and "Taint:" Hospitals Compared to Home Care

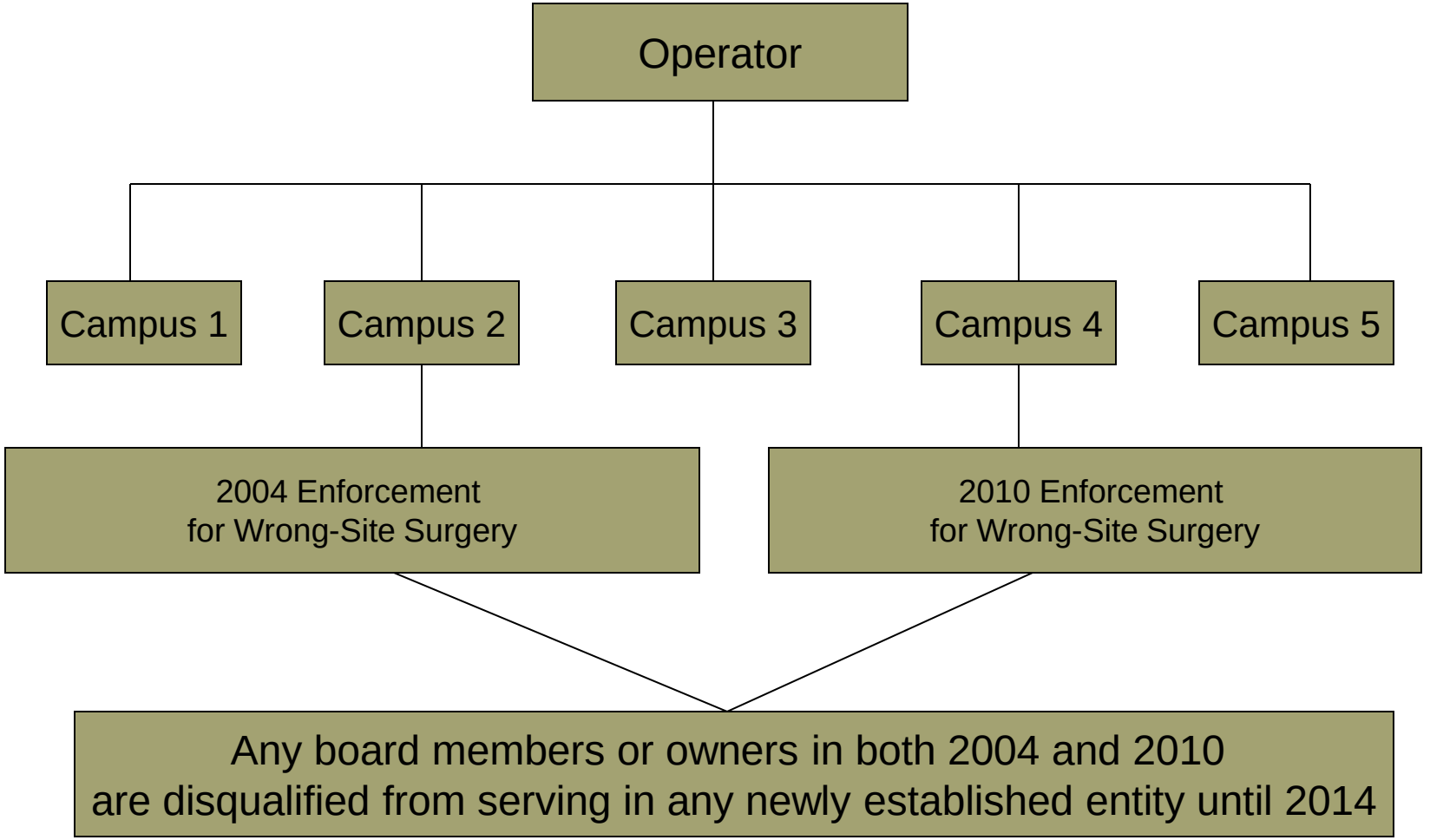
Article 28 (Hospitals, DTCs, RHCFs)	Art. 36 (CHHAs, LHCSAs)
Review all shareholders in corps., all members of LLCs.	Review all shareholders with interests > 10%, all members of LLCs.
No review of passive parents in not-for-profits.	Review passive parents, investors, "controlling persons," etc.
Statutory 10-year look-back with mandatory bar.	No statutory 10 year look-back.

Disqualification or “Taint”

- Taint: Two enforcements for the same health/safety transgression taints any board member or owner serving at the time of both violations.

- Enforcement: An action taken by DOH against a health care facility as a result of a survey or investigation resulting in a final determination. Examples include:
  - Identified patient harm or the potential for patient harm due lack of systems to prevent.
  - Repeat instances of non-compliance related to the same issue.

Case Study Applying Current "Taint" Policy



C&C Reviews: Limitations

- Difficult to assess character and competence in context of an application.
- Ill-defined affirmative requirements, e.g., types of experience required.
- Disqualification rules:
  - Disadvantage applicants with health care facility/agency experience;
  - Inflexible – may disqualify high-performing operators because of 2 isolated events.
  - Under-protective:
    - Encourage negotiations to avoid “repeat” or recurrent violations;
    - Encourage replacement of tainted individuals with inexperienced ones;
    - Encourage passive parent relationships;
    - Prevent establishment actions, but not expansions of services or capacity.

C&C Reviews: Shortcomings

- Growth of integrated systems will likely lead to more disqualifications based on repeat enforcements.
- Reviews and disqualification rules focus on individuals, without examining the role of the individual in the organization or the organization as a whole.
- No discretion - disqualification is mandatory when there are 2 health/safety enforcements within 10 years.

C&C Reviews: Shortcomings

- Significant investment of DOH staff and applicant resources:
  - High volume of applications;
  - Many with complex organizational structures and dozens of individuals in governing body.
- Benefits are difficult to measure:
  - Sentinel effect
  - Excludes individuals from facility/agency governing bodies due to:
    - Non-compliance - taint
    - Professional licensure actions
    - Failure to disclose
  - Promotes creation of capable, trustworthy governing bodies.

Updating C&C Reviews: Not-for-Profit Corporation Option

- Require established operators to conduct C&C review of new board members consistent with DOH regulations.
- Require updated C&C by established operators in the event of any establishment action (e.g., merger, acquisition, joint venture).
- Require attestation by operator regarding review.
- Coordinate with OMIG Compliance Plan submissions.

Updating C&C Reviews: Complex Organizations Option

- E.g., publicly-traded, private equity-owned, multi-state enterprises:
- Review individual board members, LLC members, owners, officers of proposed operator (regulated entity) and direct parent; and
- Attestation from ultimate parent and any shareholders/members with authority to influence its governance or operations concerning:
  - Organizational compliance history and operational track record of parent, controlling shareholders/members, and related entities;
  - C&C of controlling owners, directors and officers;
- Independent review of C&C and compliance of ultimate parent and related entities; or DOH review.

Rationalize Taint Rules

- Eliminate mandatory disqualification for 2 enforcements in 10 years.
- Create discretionary disqualification of individuals based on:
  - Pattern or multiple instances of non-compliance that threatens health/safety/welfare;
  - Consider role of individual in organization (presumption of disqualification for non-compliance, but individual can rebut);
  - Consider compliance record of organizations in which individual has served as CEO/CFO.

Rationalize Taint Rules (cont'd.)

- Discretionary disqualification of organizations
  - Operators with pattern or multiple instances of non-compliance.
  - Apply disqualification to major new services, new sites, expansions of capacity, in addition to establishment actions.

Updating C&C Reviews – Role of Quality Measures

- Growing use of standardized measures of quality
- Greater availability of data necessary to apply measures
- Challenges:
  - Which measures?
  - Which applications?
  - Process?

GOVERNANCE

Governance: Passive Parents

- Typically, appoint board of directors of not-for-profit health care facility.
- May not exercise any of the following powers:
  - appointment or dismissal of hospital management level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;
  - approval of hospital operating and capital budgets;
  - adoption or approval of hospital operating policies and procedures;
  - approval of certificate of need applications filed by or on behalf of the hospital;
  - approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;
  - approval of hospital contracts for management or for clinical services; and
  - approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

Problems with Passive Parents

- Effective control through board appointments
- Lack of accountability

Strengthen Governance: Passive Parent Options

- Clarify that appointment of top management is active parent or facility governing body responsibility.
  - Same person may not serve as passive parent CEO and facility CEO.
- No mirror boards.
- Require clinical integration among passive parents and facilities.
- Require DOH approval if 1/3 or more of board is replaced within specified period.
- Require DOH approval of passive parents.

Other Proposals to Strengthen Governance

- Mandate board, owner training

- Permit removal and appointment of board members or appointment of temporary operators by DOH in the event of consistent non-compliance, financial instability

Surveillance is the Key

- Monitoring quality of care and financial stability after approval is more effective than pre-approval screening of C&C.
- Increase penalties for non-compliance.
- Strengthen and expand the ability to revoke, suspend, limit operating certificates for governance, quality of care issues.
- Revocation, limitation of operating certificates if attestations are found to be false (10 NYCRR 600.5).
- Consider expanded use of time-limited operating certificates.

Additional Governance Issues

- System Integration Barriers
- Corporate Practice of Medicine vs. Corporate Ownership of Health Care Facilities
- De Facto D&TCs

System Integration Barriers

- Laws and regulations inhibit sharing of information among separate facilities in a single system:
  - QA info
  - Credentialing and privileging info

Corporate Practice of Medicine

- Professional misconduct under Education Law
  - Exception for practice through licensed health care facilities, HMOs, or home care agencies.
- Rationale: Licensed professionals retain control over care; not business enterprises
  - But, non-established entities participate in practice of medicine through lease of medical equipment, administrative services agreements, etc.
  - Some medical practices operate like large corporations.
- Disadvantages: Impedes certain joint ventures, capital access, delivery models.

Corporate Ownership of Health Care Facilities

- PHL 2801-a bars for-profit ownership of health care facility operators by non-natural persons.
  - Prohibition on corporate ownership of stock in corporate health care facility operators effectively bars publicly-traded corporate ownership, private equity/venture capital ownership.
  - Exception for dialysis facilities.
- Rationale: Ban promotes accountability, local control, retention of revenue in community.
- Disadvantage: Limits access to capital

De Facto D&TCs

- PHL Art. 28 requires licensure of facility engaged principally in providing services by or under supervision of a physician, including a “diagnostic center” or “treatment center.”
- 10 NYCRR 600.8 sets forth criteria defining the operation of a D&TC that would require licensure, including:
  - Relationship between patients and facility
  - Administration
  - Scope of services
  - Physical Plant

Prohibition on Revenue Sharing with Non-Established Entity

- Limits administrative services and similar arrangements with enterprises that might provide capital.
- Rationale: Prevents effective control over facility by non-established entity.
- But impedes certain joint ventures, obligated groups, access to capital.