

Making Sense of the Administrative Law Process

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I. WHY DO HEALTH LAWYERS NEED TO KNOW ADMINISTRATIVE LAW?

- A. Health care is a highly regulated industry.
 - 1. “Regulation” implies that there are administrative agencies that do the regulating and that administrative law is the framework in which those agencies operate.
 - 2. Regulatory oversight generally involves –
 - a. Adoption of regulations;
 - b. Enforcement of regulations; and
 - c. Hearing appeals on enforcement actions.

- B. Administrative agencies important to health lawyers
 - 1. Federal – sub-agencies of Department of Health and Human Services (“HHS”):
 - a. Centers for Medicare and Medicaid Services (“CMS”) – responsible for Medicare and Medicaid programs.
 - b. Office of Inspector General (“OIG”) – Civil enforcement of anti-Fraud & Abuse statutes
 - c. Food and Drug Administration (“FDA”) – oversight of development and marketing of pharmaceuticals and medical devices.
 - d. Office of Civil Rights (“OCR”) – HIPAA privacy and security regulations.
 - e. Centers for Disease Control and Prevention – public health functions
 - 2. Federal – other
 - a. National Practitioner Data Bank
 - b. Healthcare Integrity and Protection Data Bank
 - c. Department of Agriculture (handling and treatment of laboratory animals)
 - 3. Pennsylvania agencies important to health lawyers:
 - a. Department of Health (“DoH”)

- (1) Enforcement of standards for most institutional healthcare providers (hospitals, nursing homes, ambulatory surgical centers, home health agencies, etc.)
 - (2) Under contract with CMS, oversees enforcement of Medicare standards for institutional healthcare providers (“State Survey Agency”).
 - (3) Enforcement of certain quality of care standards for HMOs, PPOs, and CCRCs
 - (4) Enforcement of standards for clinical laboratories
 - (5) Public health functions
- b. Department of Public Welfare (“DPW”)
- (1) Enforcement of standards for assisted living facilities, personal care homes, and boarding homes
 - (2) Enforcement of standards for mental health facilities
 - (3) Operation of state Medical Assistance (Medicaid) program, a joint federal-state program that provides medical coverage for the very poor (“Single State Agency”).
 - (4) Supervision of public mental health programs operated by the counties
- c. Insurance Department
- (1) Licensure of Blue Cross, Blue Shield, and commercial health insurance plans
 - (2) Shares responsibility for licensure and supervision with DoH of arrangements where Insurance Department oversees management of financial risk and DoH oversees quality of care: HMOs, PPOs, CCRCs.
- d. Bureau of Professional and Occupational Affairs, Department of State –
- (1) State licensure boards oversee licensure of virtually every type of healthcare professional.
 - (2) Licensed professionals include physicians (M.D. and D.O.), dentists, nurses, clinical psychologists, podiatrists,

chiropractors, physical therapists, physician assistants, optometrists, advanced nurse practitioners.

II. A SHORT COURSE IN ADMINISTRATIVE LAW

A. Principles

1. An administrative agency derives all of its power from the Legislature, and it has the authority to do only that which the Legislature has delegated to it by statute.
2. *Legislative power* is the power to make laws. The agency's power to create regulations that have the force of law results from a delegation of a part of the Legislature's powers to the agency.
 - a. Promulgation of regulations (rulemaking) is an exercise of delegated legislative power.
 - b. The substantive scope of an agency's rulemaking power is limited to that delegated to the agency.
 - c. Procedural requirements for rulemaking are spelled out in statutes governing the rulemaking process (described in Section II.B below)
 - d. *Improper delegation*: In order for such delegation to be proper, the legislation must contain adequate standards to guide and restrain the agency's exercise of that power. *Commonwealth v. Sessoms*, 532 A.2d 775, 784 (Pa. 1987).
3. *Adjudicatory power* is the power to resolve specific matters through a quasi-judicial review of the facts and law relevant to such matters.
 - a. Agency's adjudicatory power is subject to Constitutional due process restrictions (imposed by the courts):
 - (1) Reasonable notice
 - (2) Opportunity for hearing
 - (3) No commingling of prosecutorial and adjudicatory functions
 - b. Subject to statutory requirements as well
 - (1) Federal: Administrative Procedure Act, 5 U.S.C. § 554
 - (2) Pennsylvania:
 - (a) Administrative Agency Law: 2 Pa.C.S. §§ 501-754

- (b) Regulations governing administrative practice and procedure generally: 1 Pa. Code ch. 31, 33, 35. (Individual agencies may have their own regulations that supplement or supersede these.)
 - c. Appeals from Administrative Proceedings
 - (1) Standard of review - Generally appellate in nature
 - (2) Agency will be sustained unless the agency's adjudication:
 - (a) Is not supported by substantial evidence in the record;
 - (b) Is contrary to law; or
 - (c) Is arbitrary and capricious.
 - (3) Forum
 - (a) Appeals from Pennsylvania state agencies and Board of Claims - Commonwealth Court
 - (b) Appeals from federal agency adjudication - U.S. District Court or as specified in the relevant statute

B. Regulations

- 1. There are two types of regulations:
 - a. Legislative rule:
 - (1) A rule that creates new law, rights, and duties in what amounts to a legislative act; it imposes distinct obligations on members of the public. *United States v. Yuzary*, 55 F.3d 47 (2d Cir. 1995).
 - (a) Legislative rules must be promulgated in accordance with the notice-and-comment procedures spelled out in the APA or the equivalent state statute.
 - (b) Legislative rules are binding on both the agency and the public and have the full force of law.
 - b. Interpretive rule: A clarification or explanation of an existing statute or rule, designed to apprise the public of the agency's construction of those authorities; it creates no law and has no effect beyond the statute. *La Casa Del Convalenciente v. Sullivan*, 965 F.2d 1175 (1st Cir. 1992).
- 2. Federal regulations
 - a. Substantive authority for rulemaking will be found in the statutes under which the administrative agency operates (e.g., Social Security Act for Medicare and Medicaid, Internal Revenue Code for taxes).

- b. Administrative Procedure Act, 5 U.S.C. § 553, spells out procedural requirements for adoption of regulations.
- c. Basic types of federal rules usually seen by health lawyers:
 - (1) Full Federal Register rulemaking
 - (2) Interpretive rules
 - (a) Manuals
 - (b) Centers for Medicare & Medicaid Services Rulings
 - (c) Federal Register preambles
 - (d) Agency opinions
 - (3) Negotiated rulemakings - 5 U.S.C. §§ 561-570

3. Pennsylvania regulations

- a. Statutory authority
 - (1) Substantive authority will be found in the general powers of the agency (in title 71 of Purdon's), as well as the statute creating particular powers (e.g., Healthcare Facilities Act; see 35 P.S. § 448.803).
 - (2) Procedural requirements for adoption of regulations:
 - (a) Commonwealth Documents Law, 45 P.S. § 1101 *et seq.*
 - (b) Regulatory Review Act, 71 P.S. § 745.1 *et seq.*

C. Important Concepts

1. Deference to the administrative agency

- a. Courts grant substantial deference to an agency's interpretation of the statutes it is charged with administering. However:
 - (1) No deference is due to agency interpretations at odds with the plain language of the statute itself. *Pub. Employees Retirement Sys. v. Betts*, 492 U.S. 158, 171 (1989).
 - (2) Agency statements contained in opinion letters, policy statements, agency manuals, and enforcement guidelines lack the force of law and do not warrant the level of deference granted to legislative rules. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000); *Madison v. Res. for Human Dev., Inc.*, 233 F.3d 175, 185 (3d Cir. 2000).

b. Interpretation of agency's own regulations

(1) Legislative rules

(a) Generally, the courts will defer to the agency's interpretation of its own regulations: *United States v. Larionoff*, 431 U.S. 864, 872 (1977); *Commonwealth of Pa., Dept. of Public Welfare v. Forbes Health System*, 492 Pa. 77, 422 A.2d 480 (1980).

(b) An agency's interpretation of its own regulation is not entitled to substantial deference where an alternative reading is compelled by the regulation's plain meaning or by other indications of the agency's intent at the time of the regulation's promulgation. *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142, 152-53 (3d Cir. 2004).

(2) Court need not defer to agency interpretation in case of interpretive rule:

(a) An interpretive rule that (i) contradicts the plain language of a legislative rule, (ii) has not been applied consistently, and (iii) is unreasonable, is arbitrary and capricious and subject to no deference. *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142 (3d Cir. 2004).

(b) Interpretive rules that did not exist when transactions were conducted should be received only "with whatever persuasive force they would enjoy if expressed in a brief filed in the litigation." *Health Insurance Ass'n of America, Inc. v. Shalala*, 23 F.3d 412, 425 (D.C. Cir. 1994).

(c) An interpretive rule that is inconsistent with an existing legislative regulation, is invalid. *Nat'l Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 235 (D.C. Cir. 1992).

(d) Courts must give deference to the agency but should disregard an interpretive rule if it is "unwise" or violates public policy. *Jay R. Reynolds, Inc. v. Dept. of Labor & Industry, Prevailing Wage Appeals Board*, 661 A.2d 494 (Pa. Cmwlth. 1995).

2. Exhaustion of administrative remedies

D. Federal vs. State Administrative Law

1. Joint state-federal programs (i.e., Medicaid)

- a. In these programs, deference is due to federal agency, but the State's interpretation of federal statute entitled to little if any deference. *Orthopaedic Hospital v. Belshe*, 103 F.2d 1491, 1495 (9th Cir. 1997), cert. denied, 118 S.Ct. 684 (1998).
 - b. However, when the federal statute requires the State make a determination (e.g., as to what payment rate is reasonable and adequate), deference to the state agency is appropriate. *See Hoodkroft Conv. Ctr., Inc. v. New Hampshire*, 879 F.2d 968, 972 (1st Cir. 1989), cert. denied, 110 S.Ct. 720 (1990).
2. Use of federal cases to interpret state law
- a. Principles of administrative law
 - b. Cases interpreting similar federal statutes are often useful in interpreting state statutes. *See Commonwealth of Penna. v. Monumental Properties, Inc.*, 459 Pa. 450, 461-62, 329 A.2d 812, 818 (1974).
3. *Note that state and federal administrative law are often similar, but not necessarily the same.* For example, the doctrine of improper delegation of legislative power, which is alive and well in Pennsylvania,¹ has no current equivalent in federal administrative law.

III. WHERE TO FIND REGULATIONS

- A. Initial, interim, and final publication
 - 1. Federal Register - <http://www.gpoaccess.gov/fr/index.html>
 - 2. Pennsylvania Bulletin - <http://www.pabulletin.com/>
- B. Codification
 - 1. Code of Federal Regulations (C.F.R.) - <http://www.gpoaccess.gov/cfr/index.html>
 - 2. Pennsylvania Code - <http://www.pacode.com/>

¹ *See State Board of Medicine v. Lyness*, 525 Pa. 535, 605 A.2d 1204 (Pa. 1992).