ADMINISTRATIVE LAW

WEEK SIX
Tuesday, Sept. 28, 2021
Professor Julia M. Glencer

AGENDA

6:00 to 6:30 Admin Agencies and "Soft" Law (*Set Up*)

6:30 to 7:30 Guest Speaker: Dealing with "Soft" Law in Practice

---------- BREAK ----------

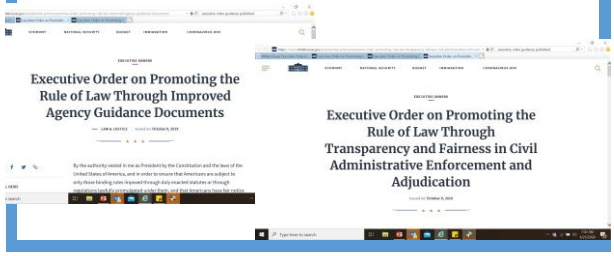
7:40 to 8:10 Getting Rule-Making Started (*New Material*)

8:10 to 9:00 Centralized Review & Cost Benefit Analysis (*Flyover*)

soft LAW.

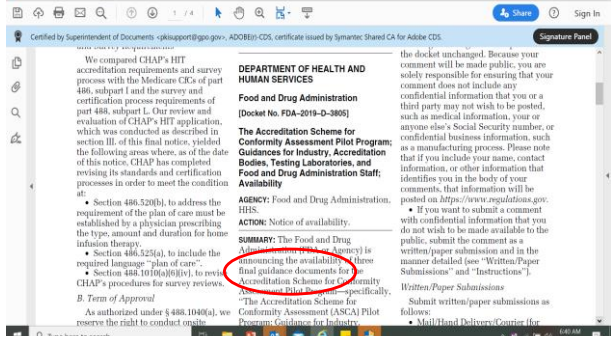
Sub-Regulatory Soft Law

FORMER EXEC. ORDERS . . .



ONE CONSTITUTION,
RATIFIED BY THE PEOPLE
Hundreds of statutes,
enacted by an elected Congress
Thousands of regulations, adopted by politically responsible agency heads

Tens of thousands of interpretations and other guidance documents, issued by agency bureaus
COUNTLESS ADVICE LETTERS, PRESS RELEASES, AND OTHER STATEMENTS, OF UNDERSTANDING GENERATED BY INDIVIDUAL BUREAUCRATS



§ 553

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EXCEPTION FOR "SOFT LAW"

Distinguish between

- Legislative rule which MUST go thru notice & comment process under Sec. 553 to have the force and effect of law

v.

- Guidance/policy statement (aka a "non-legislative rule") which does NOT need to undergo notice & comment because it fits into the exception to that process under Sec. 553(b)(A).

EXCEPTION FOR "SOFT LAW"

- Courts have called the test used to distinguish between legislative and non-legislative rules "blurred" and "baffling."
- Accepted test (take from *Gen. Elec.*) that is hard to use.
- Number of competing tests, all with problems.
- Learn the accepted *Gen Elec.* test & *American Mining*.

EXCEPTION FOR "SOFT LAW"

- *Gen. Elec.* (D.C. Cir. 2002)

"In cases where we have attempted to draw the line between legislative rules and statements of policy, we have considered whether the agency action (1) 'imposes any rights or obligations' or (2) 'genuinely leaves the agency and its decision-makers free to exercise discretion.' (textbook at 367)

(1) the admin agency's own characterization of its action;

(2) whether the action was published in the Fed. Reg. or the C.F.R. ***and***

(3) whether the action has binding effects on private parties or on the admin agency.*

- *Gen. Elec.*, textbook at 367.

- To determine whether the agency action ***binds*** private parties or the agency itself (i.e., the third factor) with the force of law, the court will ask:
  - Whether the item expresses a change in substantive law or policy which the agency intends *to make binding* or administer with *binding effect*.
    - If so, the agency must observe the APA's N &C process.

- *Gen. Elec.*, textbook at 367.

"Our cases likewise make clear that an agency pronouncement will be considered binding *as a practical matter if* it either appears on its face to be binding or is applied by the agency in a way that indicates it is binding."

- *Gen. Elec.*, textbook at 367.

AMERICAN MINING TEST

- Does the rule have "legal effect" which, "in turn, is best ascertained by asking (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the [CFR], (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is yes, we have a legislative rule."

OTHER CONSIDERATIONS?

- What is a **safe harbor** and how does that concept fit into this analysis?
- How does the concept of **pretext** (if alleged) fit into this analysis?
- How important is it to issue guidance so as to **guide lower-level agency staff** and how does that fit into the analysis?

THREE CASES . . .

Decided: Legislative rule

Decided: Guidance document

2 judges: Legislative rule
1 judge: Guidance document

- EPA, under Toxic Substance Control Act, had 2 regulations governing: (1) cleanup and disposal of PCB remediation waste & (2) disposal of PCB Bulk product waste.
- These regulations allowed applicants to apply for permission to use method OTHER THAN generic methods identified therein.
- EPA would approve applications for alternative methods that didn't pose unreasonable risk, but didn't tell applicants *how* to conduct the risk assessment.
- EPA issued PCB Risk Assessment Review ***Guidance Document*** *which* offered overview of risk assessment techniques & explained that applicants seeking to use alternative method could take either of 2 approaches; 2nd approach offered toxicity value EPA said it would accept.

- ***Guidance Document DID* purport to *bind*.**
  - D.C. Cir. highlighted repeated use of "must."
  - Noted that, while the Guidance Document gave choice of 2 approaches, didn't suggest openness to 3rd approach.
    - **KEY QUOTE**: "To the applicant reading the ***Guidance Document***, *the message is clear*: in reviewing applications the [EPA] will not be open to considering approaches other than those prescribed in the ***Guidance Document***."
  - EPA also appeared bound to accept the 2 approaches & to use the one approach's *pre-approved* toxicity value.
    - Notably, EPA *did not argue* that it had not treated the ***Guidance Document***, as binding.

- NHSTA, under Nat'l Traffic & Motor Vehicle Safety Act, oversees auto recalls for defective or substandard equipment
  - NHTSA long allowed voluntary manf'r recalls (even reg'l recalls).
- New **Guidelines** to govern 2 situations: (1) consequence of defect occur due to short-term/single exposure to particular meteorological condition; (2) consequence occurs after years of exposure.
- 1st situation: **Guidelines** said reg'l recalls NOT appropriate but NHSTA *may* act favorably on request to include language to auto owners in low risk states that defect not likely to cause problem if car not exposed to that meteorological condition.
- 2nd situation, **Guidelines** said NHTSA *might* authorize reg'l recall.
- **Guidelines**: Manf'rs must discuss all reg'l recall proposals with NHTSA.

NHTSA Guidelines DID NOT purport to bind.

- Was explicitly labeled a "policy" guideline, NOT published in C.F.R.
- Did not purport to explicitly define "rights" or "obligations."
- Read like "guidance" (i.e., conditional language & general prescriptions; no language to command, require, order, or dictate).
- Record did not indicate NHTSA officials considered themselves bound.
- NHTSA remained free to exercise discretion in assessing proposed recalls.
- Guidelines didn't allow manufacturers to rely on its terms as a "safe harbor" by which to shape their actions.*
- Didn't matter that NHSTA officials had encouraged voluntary compliance (*why wouldn't they*?)
- Admin official who wrote the **Guidelines** only had authority to issue guidance, not regulations.

- 2012 DHS created DACA Program allowing youth brought illegally to U.S. to stay without deportation & ability to work.
  - In related memo, DHS set forth how – in exercise of prosecutorial discretion – DHS should enforce immigration laws against certain young people, listing 5 criteria.
- 2014 DHS created DAPA Program, provided similar benefits to DACA to parents of children. DHS expanded DACA telling USCIS to use process to assess 5 added criteria
- 26 states sued to enjoin DAPA – numerous claims including that DAPA was legislative rule
- Court asked: (1) imposes rights & obligations; (2) genuinely leaves the agency and its decision makers free to exercise discretion.
  - Overlap if document denies discretion to agency.

- **DAPA Program DID *purport to BIND* because it removed admin agency officials' discretion.**
- Majority accepted the District Court's finding that DACA & DAPA purported to confer discretion but such was *pretext*, meaning DHA TOLD the USCIS officials how to treat applicants.
  - Small denial rate and lack of evidence that officials WERE exercising discretion.
  - The declaration of Palinkas, U Pres. representing USCIS EEs processing the applications.
    - Testified that DHS Management had taken steps to ensure that applications were basically being approved; or shall we say "rubberstamped."
    - There was conflicting evidence given by the Assoc. Director USCIS Service Operations, who said this was a case-by-case process involving exercise of discretion. The DC had apparently deemed his testimony to be less credible.
- Presidential statements in the public about DHS officials who don't follow the programs "having problems."

- Dissenting judge saw **general statement of policy**.
  - Examined face of the DACA/DAPA Memos and saw:
    - *discretion* (even use of the word discretion).
    - *guidance* to low-level agency employees (good thing, right?)
  - Certain substantive criteria required exercise of discretion:
    - "pose a danger to nat'l security"
    - "no other factors that in the exercise of discretion make the grant inappropriate"
  - DACA/DAPA Memos conferred no ability for person denied deferred action to sue over the denial; memos did not prevent officials from removing person who did satisfy the criteria.
  - Without these programs, deferrals could still occur.
  - Disputed the District Court's pretext finding; majority wrong to accept it.

EXCEPTION FOR "SOFT LAW"

- Learn the accepted *Gen. Elec.* test & the *American Mining* test used to distinguish between legislative rule vs. guidance document/policy statement.
- Recall how the courts in *Gen. Elec., Auto Safety* & *Texas* worked with those considerations.
- Realize this is *always* a contentious, very arguable issue!

GUEST SPEAKER

Partner,
Horty Springer & Mattern

NPDB Guidebook

Helpful Guidance or Impermissible Expansion of Agency Authority?

Why was the National Practitioner Data Bank ("NPDB") created?

Statute requires reports to the NPDB:

- Malpractice Payments by Insurers
- Sanctions by State Licensing Boards
- "Professional Review Actions" by "Health Care Entities"
- Fraud & Abuse Sanctions

Must Report:

- Hospitals must report "a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days…" 42 U.S.C. 11133
- "The term 'adversely affecting' includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity." 45 C.F.R. 60.3

What is a "restriction"?

- Not defined in statute
- Not defined in regulation
- Some case law, but limited to specific facts

What Is a "Restriction"?

"A 'restriction' is the result of a professional review action based on clinical competence or professional conduct that leads to the inability of a practitioner to exercise his or her own independent judgment in a professional setting."

NPDB Guidebook

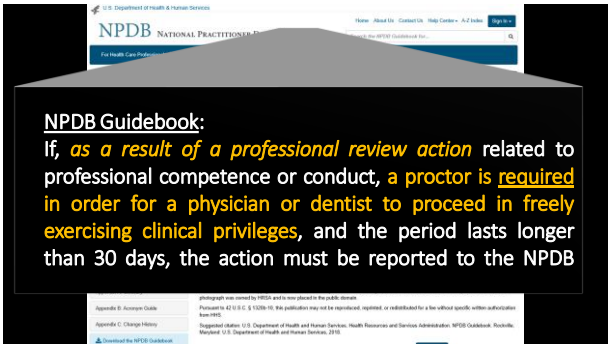
The Peer Review Clinic — Horty Springer

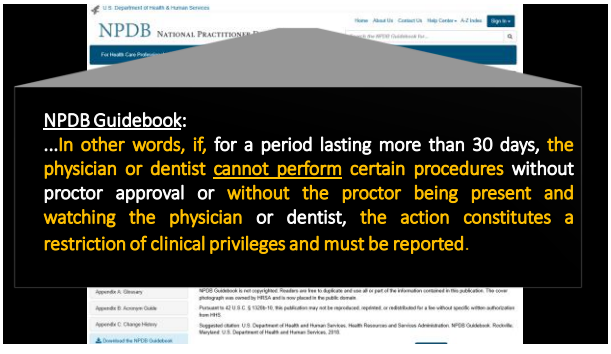
Does "proctoring" limit a physician's independent judgement?

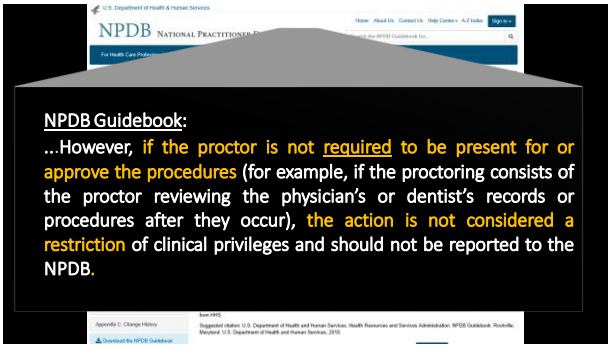
Sample Peer Review Policy – Voluntary Enhancement Plans

- Additional education
- Chart review of next X cases
- Checklist for procedures
- Second opinions
- Concurrent proctoring (i.e., observation)

The Peer Review Clinic — Horty Springer



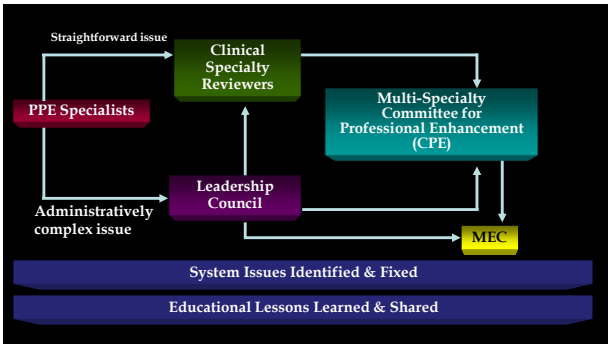




NPDB Guidebook:

...However, if the proctor is not required to be present for or approve the procedures (for example, if the proctoring consists of the proctor reviewing the physician's or dentist's records or procedures after they occur), the action is not considered a restriction of clinical privileges and should not be reported to the NPDB.

Now what, if you're the regulated industry?



COMMITTEE FOR PROFESSIONAL ENHANCEMENT ("CPE") is a peer review and quality assurance committee under state law that performs the following duties:

***

The CPE possesses no disciplinary authority. Only the Medical Executive Committee has the authority to conduct non-routine, formal investigations and to recommend restrictions of clinical privileges.

What ELSE Must Be Reported to the NPDB?

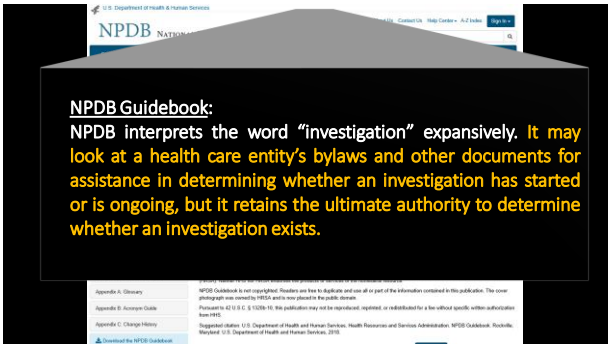
the surrender of clinical privileges of a physician -

(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or

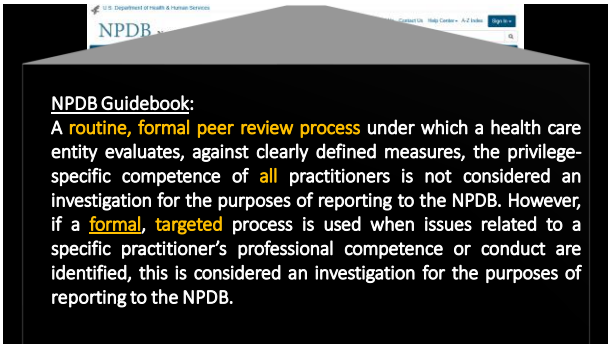
(ii) in return for not conducting such an investigation

What is an "investigation"?

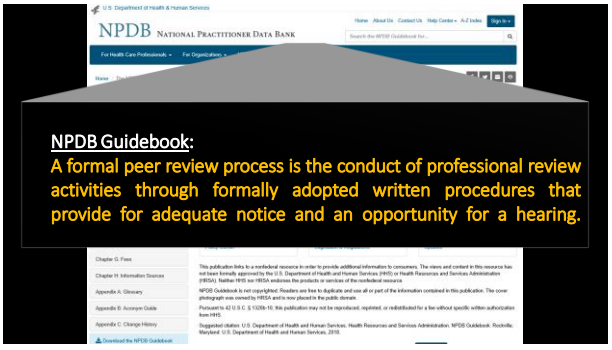
- Not defined in statute
- Not defined in regulation
- Some case law, but limited to specific facts



NPDB Guidebook:
NPDB interprets the word "investigation" expansively. It may look at a health care entity's bylaws and other documents for assistance in determining whether an investigation has started or is ongoing, but it retains the ultimate authority to determine whether an investigation exists.



NPDB Guidebook:
A routine, formal peer review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of all practitioners is not considered an investigation for the purposes of reporting to the NPDB. However, if a formal, targeted process is used when issues related to a specific practitioner's professional competence or conduct are identified, this is considered an investigation for the purposes of reporting to the NPDB.

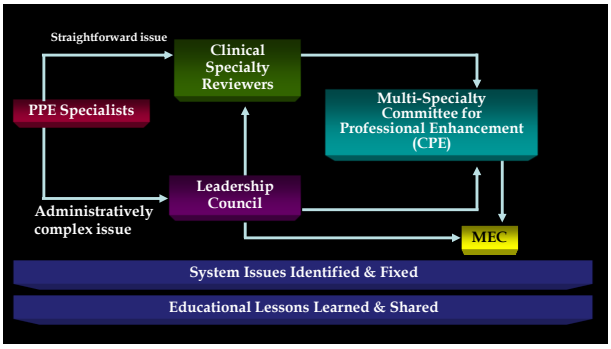


NPDB Guidebook:
A formal peer review process is the conduct of professional review activities through formally adopted written procedures that provide for adequate notice and an opportunity for a hearing.

Now what, if you're the regulated industry?

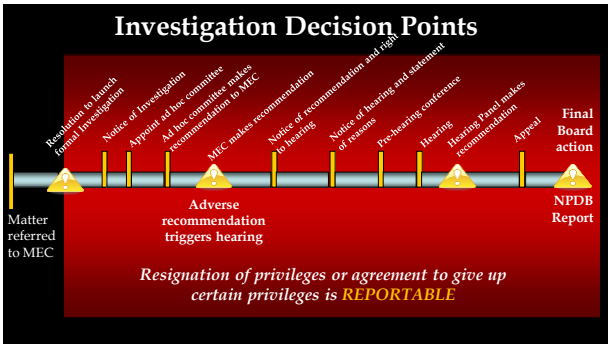
Using Hospital Policies to Provide Clarity on Investigations

- Create separate, "informal" peer review process
- Informal process cannot result in restrictions of privileges, so there are no hearing procedures



Using Hospital Policies to Provide Clarity on Investigations

- State in Bylaws that only the MEC or Board can begin investigation
- No other committees have "disciplinary authority" (e.g. they only handle collegial process)



Sample Bylaws Language: Initiation of Investigation:

The Medical Executive Committee will review the matter in question, may discuss the matter with the Practitioner, and will determine whether to conduct an Investigation or direct that the matter be handled pursuant to another policy. An Investigation will commence only after a determination by the Medical Executive Committee or the Board.

Representing the Regulated Industry

- How much weight should be given to sub-regulatory guidance?
  - Risk of not complying? (Compare NPDB violations to Stark law violations)
  - Benefits of not complying? Is the government simply wrong?
  - Willingness of client to be a "test case"

Representing the Regulated Industry

- What do you tell the client?
  - Clients unlikely to care about the nuances; they want an answer from you
  - Having J.D. after your name gives you instant credibility
  - Partly a matter of personal preference; some attorneys discuss grey areas more than others

Questions?

Thank You!

NUVANCE HEALTH HORTY SPRINGER

BREAK TO 7:40 p.m.

CH. IV, SEC. 4: GETTING RULE-MAKING STARTED

Initiation of Rule-Making
Negotiated Rule-Making
Centralized Planning & Review
Cost/Benefit Analysis (CBA)

RULE-MAKING INITIATION

- Rule-making gets started in one of three ways:

(1) Initiation *within* the admin agency
(2) Initiation by the public (via Sec. 553(c))
(3) Initiation via the "negotiated rule-making" process

*Congress can *compel* and/or prompt (1) & (3).
*White House can direct and/or prompt (1) & (3).

PUBLIC INITIATION THRU § 553(e)

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

To be read in conjunction with § 555(e), which provides:

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

BEHIND-THE-SCENES . . .

- Admin agencies vary greatly in terms of
  - setting priorities for rule-making
  - following processes to actually create rules (hard & soft)
  - allocating resources (money & people) to rule-making.
- Some bigger admin agencies have devoted rule-making offices
- Usually follow a "work plan" and use smaller "working groups"
- Often seek informal input from centralized reviewers early in the process
- Many admin agencies have dedicated legal counsel to assist
- Rise in "tiered approach" (i.e., tailoring based on magnitude & complexity of the rule-making & the expectation of challenge)

NEGOTIATED RULE-MAKING

- Negotiated Rulemaking Act, added in 1990 to the APA (5 U.S.C. §§ 561-70a).
- Mechanism for generating proposals, not final regulations.
- Neg/Reg championed where feasible by Exec. Order 12866.

CH. IV, SEC. 4: GETTING RULE-MAKING STARTED

Initiation of Rule-Making
Negotiated Rule-Making
Centralized Planning & Review
Cost/Benefit Analysis (CBA)

MAIN PLAYERS IN CENTRALIZED REVIEW

- OMB (Office of Management and Budget)
- OIRA (Office of Information and Regulatory Affairs, which is part of OMB)

About OIRA – History

(OIRA, pronounced "oh-eye-ruh") is a Federal office that Congress established in the 1980 Paperwork Reduction Act . . . OIRA is part of the . . . (OMB) . . . In addition to reviewing government collections of information from the public under the Paperwork Reduction Act, OIRA reviews draft proposed and final regulations under Executive Order 12866 and develops and oversees the implementation of government-wide policies in the areas of information policy, privacy, and statistical policy. . . .

"Obscure but powerful . . . denotes a fundamental conflict . . . [because it] runs counter to the general predilection . . . in favor of openness, particularly for offices that exercise significant authority. Obscure but powerful . . . connotes an unsettling state of affairs, and that is exactly what is meant when the phrase is used by Ds to describe OIRA under a R administration. To a[n R] administration, however, OIRA is obscure and powerful, though usually not as powerful as some . . . would wish. During D administrations, OIRA is still obscure (though not obscure enough for many . . .) but its power is controlled . . . To Rs during a D administration, OIRA's obscurity connotes a power that should be – but is not – used, which to the Washington cognoscenti is the same as not having any power at all."

Donald R. Arbuckle, *Obscure but Powerful: Who Are Those Guys?*, 63 Admin. L. Rev. 131, 133 (2011) (Rs & Ds added to save space!)

"OIRA's daily work actually is . . difficult, complex, frustrating, and demanding analytic work in the vast briar patch of executive branch regulatory detail. It turns out that scarcely anyone is actually interested in the details of this work. Few have the interest, the stamina, or the will to labor thus among the thorns."

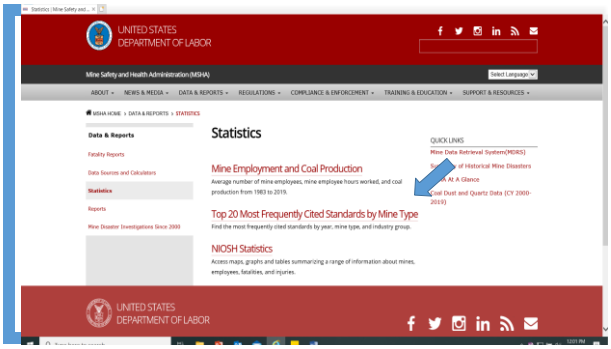
Donald R. Arbuckle, *Obscure but Powerful: Who Are Those Guys*?, 63 ADMIN. L. REV. 131, 134 (2011).

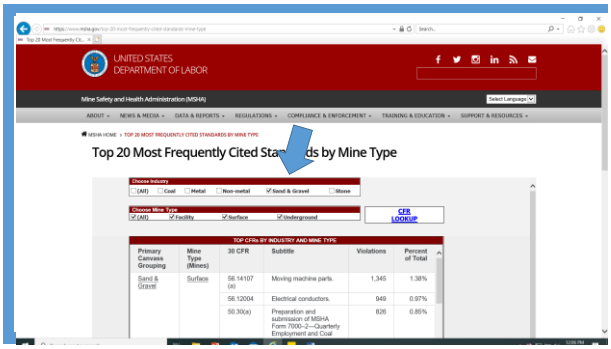
BASIC TIME LINE Centralization

- Pres. Carter, Exec. Order 12044 – requiring analysis of economic impact of certain important rulemakings.
- OIRA created by Congress in 1980 in Paperwork Reduction Act.
- Pres. Reagan, Exec. Order 12291 & 12498 – placed wider range of rule-making activities under OIRA's supervision and created analytic requirements.
- Pres. Reagan Exec. Order 12498 created annual regulatory agenda (under OIRA supervision).
- Pres. Clinton Exec. **Order 12866** (Oct. 4, 1993) – said to build on Reagan's legacy of centralized control via regulatory planning (Unified Regulatory Agenda & individual admin agency "Regulatory Plan")

BASIC TIME LINE Centralization

- Pres. George W. Bush kept Exec. Order 12866, but added Exec. Order 13422 which made 4 changes:
  (1) Included significant guidance documents
  (2) Heightened the specificity of certain analysis requirements
  (3) Enlarged the role of each admin agency's regulatory policy officer & made that officer a Presidential appointment
  (4) Required admin agencies to consider using FORMAL rule-making.
- Pres. Obama revoked Exec. Order 13422; restored the Clinton's Exec. Order 12866
  - Added Exec. Order 13563 to emphasize public participation in rule-making & foster retrospective analysis of existing rules to determine if outmoded, ineffective, insufficient or excessively burdensome.
  - Supplemented with memo urging admin agencies to make their rule-making and compliance activities, accessible, downloadable and searchable on-line.





BASIC TIME LINE Centralization

- Pres. Trump did not rescinded Exec. Order 12866 (Pres. Clinton, reinvigorated by Pres. Obama) nor Exec. Order 13563 (Pres. Obama)
  - Did add Exec. 13771 to require "the 2:1 deal" (eliminate 2 regulations for every new 1) and to set a "regulatory budget" per admin agency. (rescinded by President Biden)
  - Now we know he added two Exec. Orders on soft law:
    - Exec. Order 13891 (rescinded by President Biden)
    - Exec. Order 13892 (rescinded by President Biden)

BASIC TIME LINE Centralization

- What has **President Biden** contributed to centralization?
  - Regulatory Freeze Memorandum: "temporarily stops the regulatory and guidance pipeline" (that's pretty typical).
  - Presidential Memorandum (being called the "*Modernization Memo*")
    - Embraces Exec. Order 12866 (Pres. Clinton's) & Exec. Order 13563 (Pres. Obama's).
    - Directs OMB to produce recommendations to improve and modernize regulatory review.
      - Directs OMB to revise Circular A-4 which is OMB's internal "playbook" for how to conduct regulatory analysis.
      - Calls for procedures to take into account the "distributional consequences of regulations" (i.e., paying more attention to who bears the costs/ who reaps the benefits of proposed regulations)
      - Directs OMB to "determine the appropriate approach with respect to the review of guidance documents" (Look! A concern with soft law!)
      - Seems to position OIRA to assume a more pro-active role in regulatory planning . . .

- "Under the [*Modernization Memo*], OIRA is directed to partner with [administrative]agencies to 'explore, promote, and undertake regulatory initiatives that are likely to yield significant benefits.'"
  - Is OIRA big enough/outfitted with enough resources to assume such a role?
  - Likely is very efficient to invite its "cross-governmental perspective" and expertise into the process of rule-making from the very start.
    - Bridget C.E. Dooling, *The Regulatory Savvy of Biden's Early Executive Actions* (Brookings, Jan. 26, 2021).

CENTRALIZED REVIEW

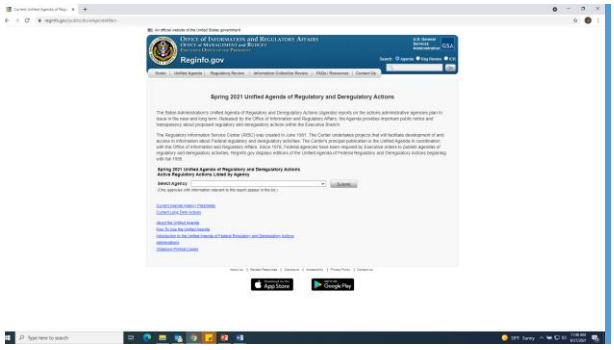
- Is subject to an overarching question of *whether this kind of Presidential oversight is even appropriate . . .*
  - Does it foster a separation of power problem vis-a-vis the other branches in that it creates a form of "presidential veto" of rule making?
  - Does it just create another forum for political wrangling?
    - Story of Bush White House willing away scientific & regulatory analysis it didn't like by refusing to open e-mail from the EPA?
    - Story of Obama White House delaying certain controversial rules to avoid controversy during re-election campaign?

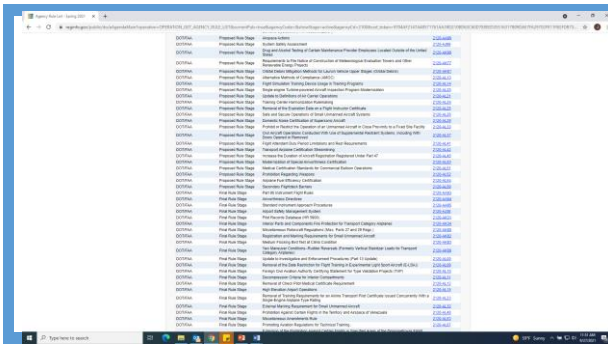
CENTRALIZED REVIEW

- Admin agencies must identify "all regulations under development or review' for inclusion in **semi-Annual Unified Regulatory Agenda**.
- Admin. agencies must also prepare a **Regulatory Plan** identifying the most significant regulatory actions it expects to issue in proposed or final form that year, identifying for each:
  - Objectives, need, alternatives, estimates of costs & benefits.

Benefits of this kind of planning:

- creates greater public awareness of rulemaking activity
- helps admin agency heads know about & prioritize rulemaking
- improves budgetary management
- helps identify and avoid inter-agency policy conflict





CENTRALIZED REVIEW

- **Exec. Order 12866** build the centralized review regime based on categories with most requirements for "*significant regulatory action*" which is defined 4 ways:
  - Projected annual effect on economy of $100 million plus
  - Projected to create inconsistency with other agency action
  - Projected to materially alter budgetary impact of entitlements, grants, user fees, loan programs, or rights/obligations of recipients thereof
  - Will raise novel legal or policy issues

MECHANICS OF OIRA REVIEW

- Review the Chart on page 421 for the formal process
- Assignment of OIRA "desk officers"
  - Review cited authority & all regulatory statements (including CBA analysis)
  - Consult with budget side of OMB & seek "sign off"
  - Consult with other OIRA staff with expertise in stats, surveys, tech, privacy
  - Consult with other parts of Exec. (outside councils, other agencies, Pres.)
  - Communicate with the admin agency
    - Often telephone & e-mail
    - Sometimes briefings/meetings
    - Sometimes drafts passed to & fro

MECHANICS OF OIRA REVIEW

- You can track OIRA's formal review process on reginfo.gov (but not its *informal* process)
- OIRA staff has varied expertise
  - Historically in economics,
  - Now increasingly in science-based, social regulation
  - Is considered to be an expert in the field of regulation itself!

CENTRALIZED REVIEW

Always questions about:

- Transparency of the centralized review process
- True extent of OIRA's influence on regulatory outcomes
- Whether the delay associated with centralized review is worth it (it can add years)
- Whether centralized review really does foster improved quality, consistency & coherence
- Whether centralized review is anti-regulatory by nature

CENTRALIZED REVIEW

Two Final Intriguing Points:

- "[T]he very existence of external (centralized) review can *improve* an [admin] agency's decision-making process by keeping the [admin] agency on its analytical toes."
  - *Do you agree?*
- EPA has built a substantial in-house economics capacity that "far dwarfs that of OIRA."
  - *What impact might this have?*

CH. IV, SEC. 4: GETTING RULE-MAKING STARTED

Initiation of Rule-Making

Negotiated Rule-Making

Centralized Planning & Review

Cost/Benefit Analysis (CBA)

COST/BENEFIT ANALYSIS

- CBA is a prominent feature of the rule-making, regulatory review process.
- CBA typically requires *both* costs and benefits to be assessed, *both* quantitatively and qualitatively.
- Generally, the benefits should justify the costs and the analysis should be explainable.

COST/BENEFIT ANALYSIS

- CBA is required (often by statute in certain Acts) and by Exec. Order for certain categories of rules ("significant").
- CBA *is* time and resource intensive.
- Quantification can be hard and it often comes down to ranges and guesses.
- CBA requires assigning monetary value; that can require an imaginary "market" for items like good health, long life, clean air, the avoidance of rape.

COST/BENEFIT ANALYSIS

- Important: In some circumstances Congress – via statute – has forbidden or limited how costs are to be taken into account in regulating health and safety issues.
- But then, Exec. Order 12866 might still require it.

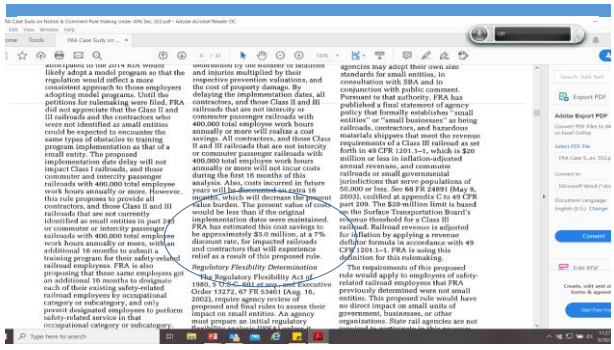
COST/BENEFIT ANALYSIS

Concerns

- Is it foreign to how normal humans assess risk and thus makes admin agencies seem a little nutty?
- Downplays context & undermines fairness/protection?
- Is anti-regulatory and harms pro-regulatory interests?
- Could be used to spur as well as check agency action?
- Could be better used to distribute the benefits and burdens of regulation?
- Is a poor fit for certain kinds of regulation? (*financial*)

COST/BENEFIT ANALYSIS

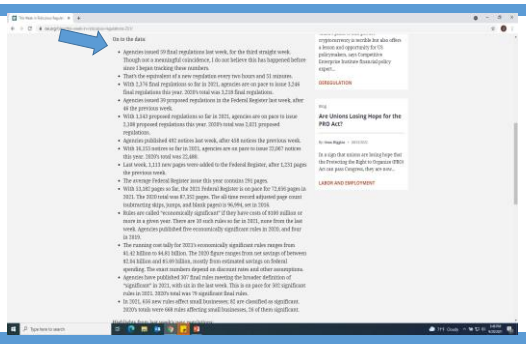
- Admin agencies *must* prioritize which risks merit regulation and how to prioritize the risks on that list.
- Some support increased role for OIRA in centralizing risk assessment and priority setting:
  - especially where "science" involved.
  - especially where numerous "single mission" agencies are addressing related, complex risk
- Some support independent, external peer-review

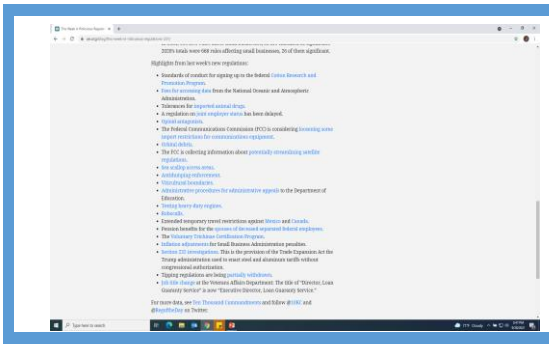


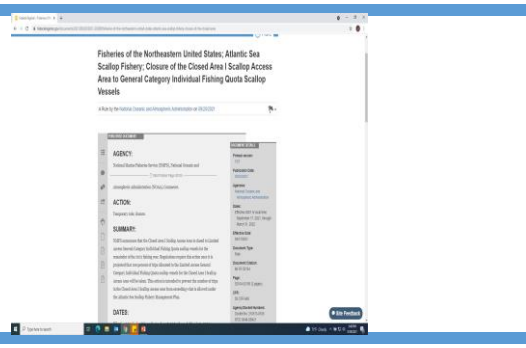
COST/BENEFIT ANALYSIS

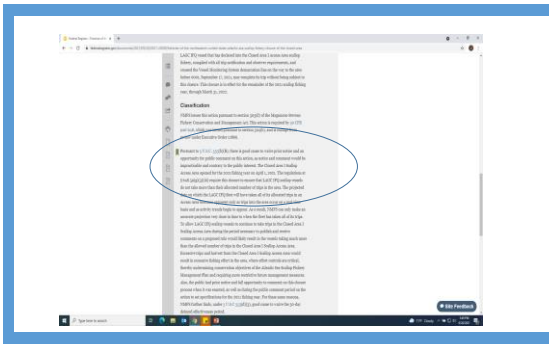
- "Once a cost benefit analysis is performed, its bottom line number offers an irresistible sound bite that inevitably drowns out more reasoned deliberation."

-Bruce Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. REV. 1553, 1583 (2002).









8. The Fourth Amendment to the United States Constitution –

A. Prohibits Congress from arming an administrative agency with the power to commit warrantless inspections of private property;

B. Does not require a warrant where Congress has determined that an administrative agency must be able to conduct warrantless inspections in order to further a regulatory scheme;

C. Does not necessarily require a warrant where Congress has determined that warrantless inspections by an administrative agency are necessary to further a regulatory scheme and where the inspection program is sufficiently comprehensive and known to the property owner;

D. Has been interpreted to impose no restrictions on the annual inspection of pervasively regulated industries such as coal mining, amusement parks, and automobile salvage facilities by the administrative agency overseeing that industry.