# Administrative Law

Dianne Oster,
Serials/GovDocs Librarian
Seton Hall University School of Law
Peter W. Rodino, Jr. Law Library
osterdia@shu.edu

2 principal sources for Federal rules and regulations are the **Federal Register** and the **Code of Federal Regulations**.

Rules and Regulations mean the same thing for the purposes of Administrative Law.

All Administrative Law gets Authority from the underlying statutes.

Regulations govern all aspects of our lives--

Building construction, safety of food, roads we drive on, cars we drive in, products we have in our homes, means of communication between us and the outside world.

**When a federal law is enacted it may require various governmental agencies to issue regulations to carry out that law. The Federal Register is the official vehicle used to notify the public of those regulations. Hence it is called "quasi-legislative."**

# Administrative sources

| Chronological Compilation | Subject Compilation |
| --- | --- |
| Federal Register (F.R.) | Code of Federal Regulations (C.F.R.) |
| New Jersey Register (N.J.R.) | New Jersey Administrative Code(N.J.A.C.) |

FAA
FCC
FDA
NLRB
NRC
USAF

EPA
SEC


ATF
DOT

GSA
IRS
NASA
NIH

USDA
VA

An alphabet soup of administrative agencies

## Federal Register

Proposed changes to existing regulations and new regulations are published in the Federal Register (FR). Update status and language of regulations found in the CFR by consulting the Federal Register. Published each day of the week (Mon.-Fri) except holidays.

**Also contains:**

--Notices of meetings
--Hearings
--Adjudicatory Proceedings
--Text of Presidential Proclamations
--Executive Orders

**Code of Federal Regulations** (CFR) – codification of all the regulations in force promulgated by the executive branch and independent agencies of government with **general applicability and continuing legal effect.**

Arranged in 50 titles by agency updated yearly. Between updates Federal Register should be consulted for additional rulemaking.

**Title 1 through Title 16 as of January 1**
**Title 17 through Title 27 as of April 1**
**Title 28 through Title 41 as of July 1**
**Title 42 through Title 50 as October 1**

Home

FDsys:
GPO's Federal Digital System
About FDsys
Search Government Publications
Browse Government Publications
FDsys Tutorials

Customers
Find the latest GPO Services & Products

Vendors
Find out how you can Do Business with GPO

Libraries
Find information about Federal depository libraries & the Catalog of U.S. Government Publications

GPO Quick Links
- XML Bulk Data Repository
- U.S. Government Bookstore
- Ben's Guide to U.S. Government for Kids
- Catalog of U.S. Government Publications



FDSYS FEDERAL DIGITAL SYSTEM
AMERICA'S AUTHENTIC GOVERNMENT INFORMATION

Search Government Publications
SEARCH
Advanced Search
Retrieve by Citation
Help

Legislation to Change the Name of GPO
**Government Publishing Act of 2014**
**S. 1947 (IS)**
PDF >
Text >
XML >

Farm Bill Passed By Congress
**Agricultural Act of 2014**
**H.R. 2642 (ENR)**
PDF >
Text >
XML >

Health Care Law
**Patient Protection and Affordable Care Act**
**Public Law 111-148**
PDF >
Text >

Browse
- Code of Federal Regulations
- Compilation of Presidential Documents
- Congressional Bills
- Congressional Documents
- Congressional Hearings
- Congressional Record
- Congressional Reports
- Constitution of the United States America: Analysis and Interpreta
- Economic Indicators
- Federal Register
- Public and Private Laws
- United States Code
- United States Courts Opinions
- Browse All

Moments in History
- Post JFK Assassination Audio T Recordings
- President Nixon's Watergate Gr Jury Testimony Transcripts
- The 9/11 Commission Report
- The Financial Crisis Inquiry Rep
- President Obama's Public Pape

79 Fed.Reg.12134



travel industry, as well as the FAA and Pipeline and Hazardous Materials Safety Administration. The ARC now seeks input from the general public and is particularly interested in feedback from entities subject to passenger notification regulations prescribed by U.S. Hazardous Materials (49 CFR 175.25). We note that operators transporting passengers in commerce under 14 CFR parts 135 and 91 are subject to the noted 49 CFR regulation, and it is important that a final AC provide a clear, acceptable, and effective means for these operators to communicate hazardous materials regulations to their passengers.

The ARC will review all comments received and consider them in its final recommendation to the FAA.

Issued in Washington, DC, on February 26, 2014.

Christopher Glazow,

*Director, Office of Hazardous Materials Safety.*

[FR Doc. 2014–04309 Filed 3–3–14; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 15

[Docket No. FDA–2013–N–0745]

## Action Plan for the Collection, Analysis, and Availability of Demographic Subgroup Data in Applications for Approval of Food and Drug Administration-Regulated Medical Products; Notice of Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on the issues and challenges associated with the collection, analysis, and availability of demographic subgroup data in applications for approval of FDA-regulated human medical products.

DATES: The public hearing will be held on April 1, 2014, from 9 a.m. to 3 p.m. Submit electronic or written requests to make oral presentations at the hearing by March 21, 2014. Electronic or written comments will be accepted after the hearing until May 16, 2014.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public hearing participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the corresponding docket number for the public meeting as follows: "Docket No. FDA–2013–N–0745, Action Plan for the Collection, Analysis, and Availability of Demographic Subgroup Data in Applications for Approval of FDA-Regulated Human Medical Products, Public Hearing."

FOR FURTHER INFORMATION CONTACT: Brenda Evelyn, Office of the Commissioner, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2303, Silver Spring, MD 20993 240–402–4201, email: *FDASIA907@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

### I. Background

In section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), the U.S. Congress directed FDA to produce a report that addressed the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups, including sex, age, race, and ethnicity, is included in applications submitted to FDA. Specifically, Congress asked FDA to consider four key topic areas: (1) A description of existing tools to ensure submission of demographic information along with how information about differences in safety and effectiveness of medical products according to demographic subgroup is made available to health care providers, researchers, and patients; (2) an analysis of the extent to which demographic data subset analyses are presented in applications; (3) an analysis of demographic subgroup representation in clinical trials submitted to FDA in support of product applications; and (4) an analysis of the extent to which a summary of product safety and effectiveness data by demographic subgroup is made available to the public in product labeling or on FDA's Web site.

To comply with that request, in August 2013, FDA published a report "Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products." [1] The report describes the Agency's evaluation of 72 applications approved during 2011 for new molecular entity drug products, original biologics, and class III devices (premarket approval).

Regarding collection of data, although there was variation by product area, the evaluation found FDA's statutory and regulatory requirements, guidances, policies, and procedures generally informed sponsors about including tabulations of the demographic data on clinical trial participants and demographic subset analyses in their medical product applications.

Similarly, tools (e.g., application review templates and FDA standard operating policies and procedures) guide regulatory review staff in the assessment of marketing applications to ensure that demographic data and subset analyses are included in the information FDA uses in its review and approval processes.

However, the extent to which demographic subset data were analyzed varied across medical product types (drugs, biologics, and devices). Applications for drugs and biologics uniformly addressed subset analyses by sex, race, and age—that is, the applications mentioned demographic subsets in some way. The report noted that FDA's new drug application regulations (21 CFR part 314; specifically § 314.50) call for demographic analysis in all applications in the integrated summaries of safety and effectiveness. Guidance and standard operating procedures for drugs and biologics also emphasize the importance of such analyses. There are no regulations requiring demographic analysis for device applications. Nonetheless, the majority of the device applications contained a subset analysis for age and sex, with a lower percentage of applications containing a subset analysis for race and ethnicity. Inclusion did not necessarily mean that the data on patient subgroups was sufficient for meaningful analysis or to detect relevant subgroup effects.

The report stated that all biologics, drugs, and the majority of the medical

[1] FDA, "Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products," August 2012, available at *http://www.fda.gov/downloads/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm365414.pdf.*

Regulations.gov (current) is a one stop site to comment on proposed federal regulations. It also provides easy access to proposed regulations by agency, by topic, or by keyword.

By law, the Federal Register is required to provide a chance for the public to comment on proposed regulation or regulatory changes. This website makes this process convenient.

## Commenting on Proposed Regulations

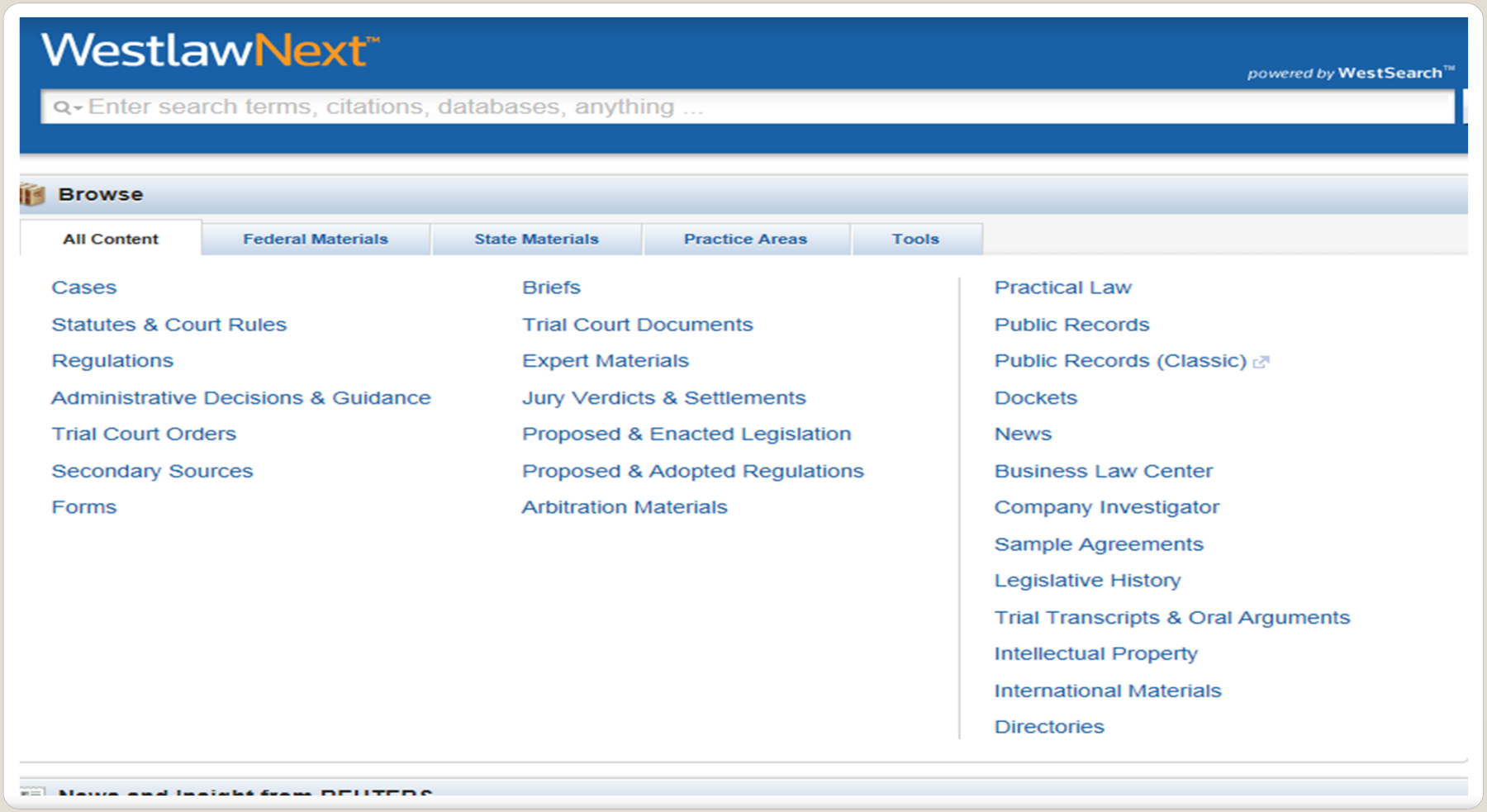
Proposed new regulations or changes to existing regulations are published in the *Federal Register* to give affected and interested parties an opportunity to comment.

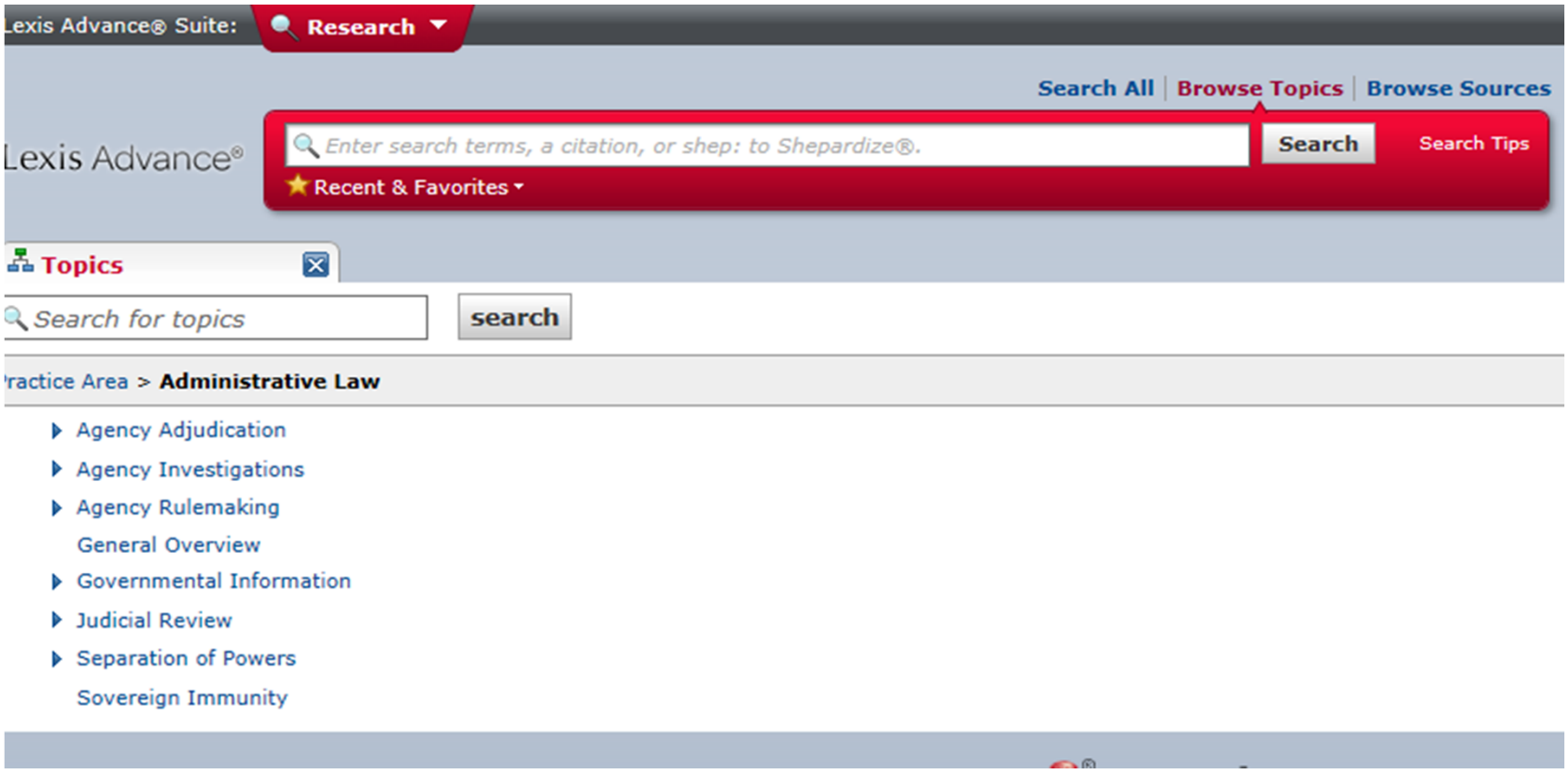
Traditionally, people submitted comments to proposals by mailing letters to the specific agency addresses provided in *Federal Register* notices. Now, agencies also solicit and accept comments by email and through the Internet.

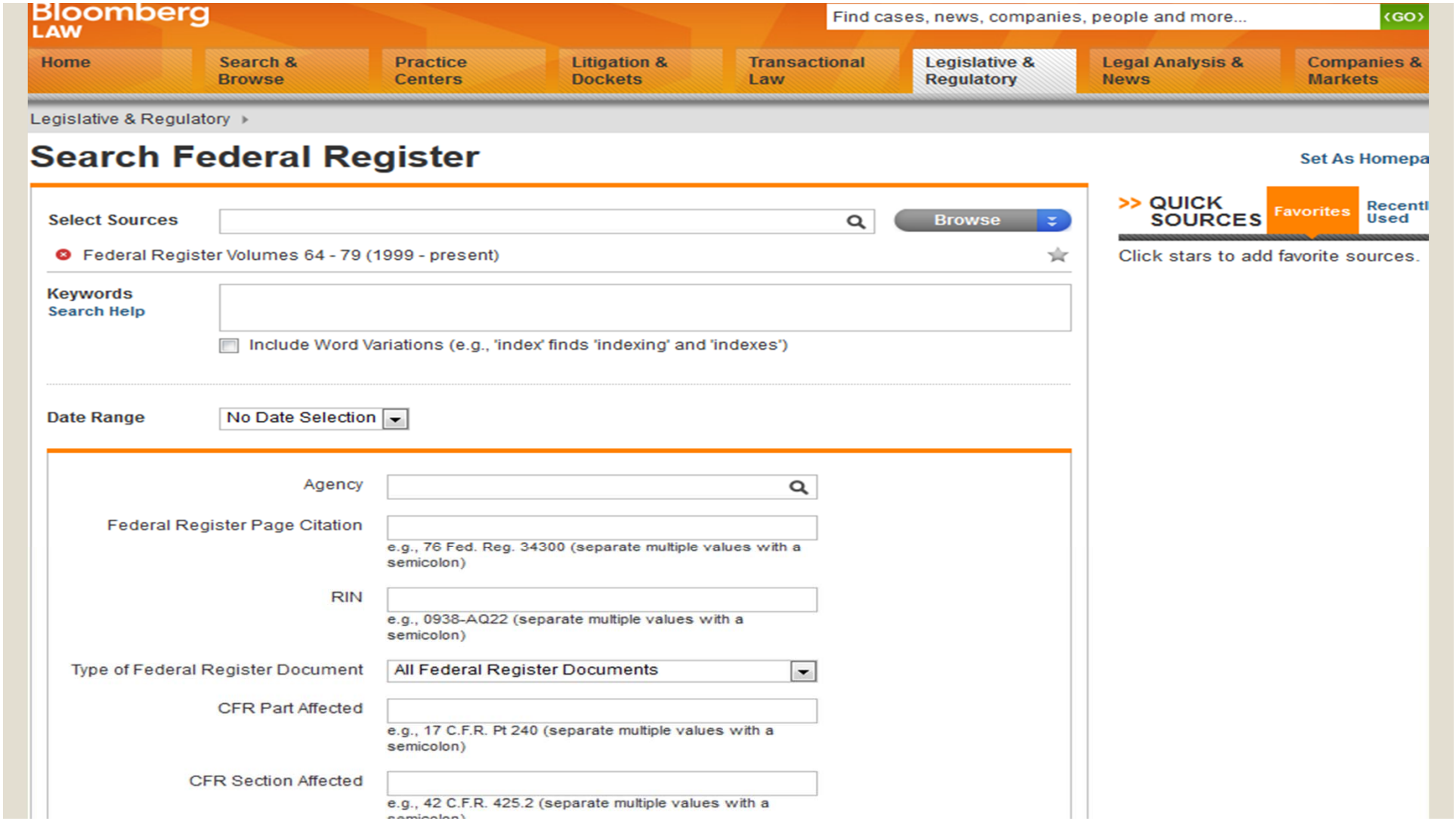
regulations.gov
Your Voice in Federal Decision-Making

Regulations.gov is a searchable collection of proposed regulations that are currently open for comment. This site includes most (but not all) proposed regulations published in the *Federal Register*, but it doesn't stop there. People can respond on the website to proposed regulations and they can see comments left by others.

Click on the Help link to view a tutorial on using the site and for a glossary of terms. Includes Tips for Submitting Effective Comments.


WestlawNext™
powered by WestSearch™
Enter search terms, citations, databases, anything ...
Browse
All Content
Federal Materials
State Materials
Practice Areas
Tools
Cases
Statutes & Court Rules
Regulations
Administrative Decisions & Guidance
Trial Court Orders
Secondary Sources
Forms
Briefs
Trial Court Documents
Expert Materials
Jury Verdicts & Settlements
Proposed & Enacted Legislation
Proposed & Adopted Regulations
Arbitration Materials
Practical Law
Public Records
Public Records (Classic)
Dockets
News
Business Law Center
Company Investigator
Sample Agreements
Legislative History
Trial Transcripts & Oral Arguments
Intellectual Property
International Materials
Directories


Lexis Advance® Suite:
Research
Search All
Browse Topics
Browse Sources
Lexis Advance®
Enter search terms, a citation, or shep: to Shepardize®.
Search
Search Tips
Recent & Favorites
Topics
Search for topics
search
ractice Area > Administrative Law
Agency Adjudication
Agency Investigations
Agency Rulemaking
General Overview
Governmental Information
Judicial Review
Separation of Powers
Sovereign Immunity


Bloomberg LAW
Find cases, news, companies, people and more...
GO
Home
Search & Browse
Practice Centers
Litigation & Dockets
Transactional Law
Legislative & Regulatory
Legal Analysis & News
Companies & Markets
Legislative & Regulatory
Search Federal Register
Set As Homepa
Select Sources
Browse
Federal Register Volumes 64 - 79 (1999 - present)
Keywords
Search Help
Include Word Variations (e.g., 'index' finds 'indexing' and 'indexes')
Date Range
No Date Selection
Agency
Federal Register Page Citation
e.g., 76 Fed. Reg. 34300 (separate multiple values with a semicolon)
RIN
e.g., 0938-AQ22 (separate multiple values with a semicolon)
Type of Federal Register Document
All Federal Register Documents
CFR Part Affected
e.g., 17 C.F.R. Pt 240 (separate multiple values with a semicolon)
CFR Section Affected
e.g., 42 C.F.R. 425.2 (separate multiple values with a
>> QUICK SOURCES
Favorites
Recentl Used
Click stars to add favorite sources.

## ADMINISTRATIVE DECISIONS

Substantive agency decisions are potentially available in four different places:

full text online using Lexis and Westlaw

the agency's Web site

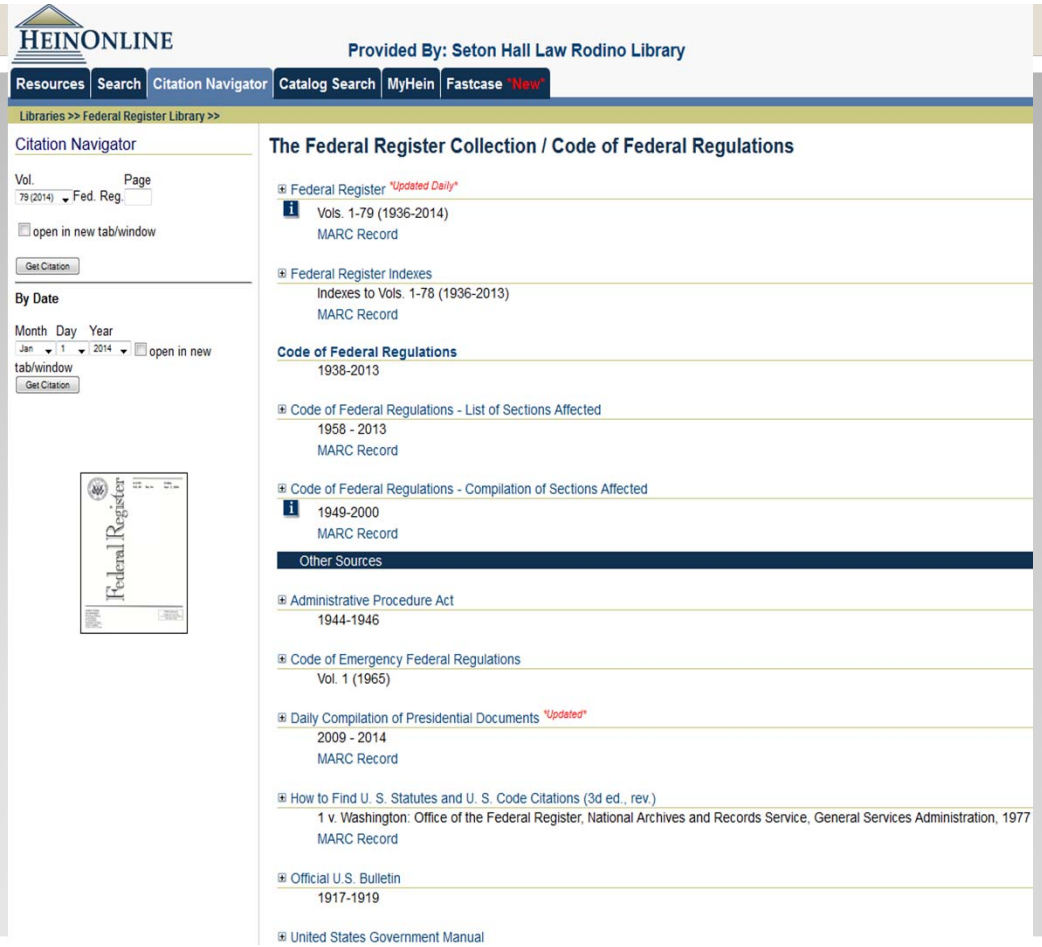
looseleaf services

officially published reports of decisions

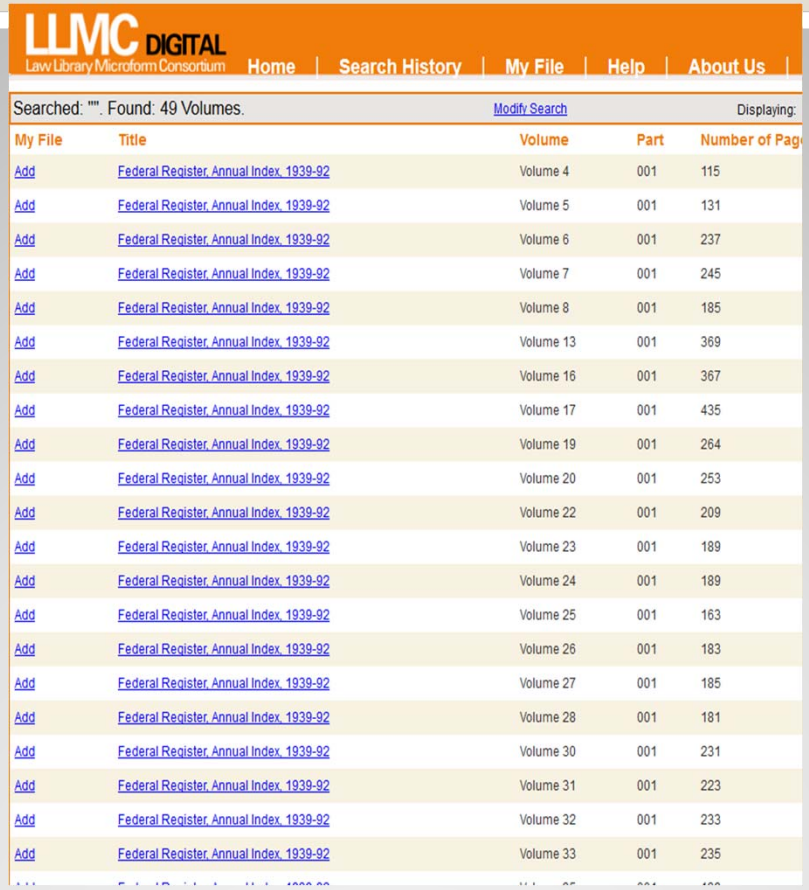
Publication of administrative decisions is more fragmented than rules and regulations, and there is no one place where all such decisions are located. In fact, some agencies do not publish their decisions in any format.

- Adminstrative decisions can be referred to as “quasi-judicial” because the agency was given the authority by Congress to adjudicate “contested cases.”

HeinOnline


HEINONLINE
Provided By: Seton Hall Law Rodino Library
Resources
Search
Citation Navigator
Catalog Search
MyHein
Fastcase *New*
Libraries >> Federal Register Library >>
Citation Navigator
Vol.
Page
79 (2014)
Fed. Reg.
open in new tab/window
Get Citation
By Date
Month
Day
Year
Jan
1
2014
open in new tab/window
Get Citation
Federal Register
The Federal Register Collection / Code of Federal Regulations
Federal Register *Updated Daily*
Vols. 1-79 (1936-2014)
MARC Record
Federal Register Indexes
Indexes to Vols. 1-78 (1936-2013)
MARC Record
Code of Federal Regulations
1938-2013
Code of Federal Regulations - List of Sections Affected
1958 - 2013
MARC Record
Code of Federal Regulations - Compilation of Sections Affected
1949-2000
MARC Record
Other Sources
Administrative Procedure Act
1944-1946
Code of Emergency Federal Regulations
Vol. 1 (1965)
Daily Compilation of Presidential Documents *Updated*
2009 - 2014
MARC Record
How to Find U. S. Statutes and U. S. Code Citations (3d ed., rev.)
1 v. Washington: Office of the Federal Register, National Archives and Records Service, General Services Administration, 1977
MARC Record
Official U.S. Bulletin
1917-1919
United States Government Manual

# LLMC Digital



**New Jersey Register**
**New Jersey Administrative Code**

The two publications dealing with administrative law in the state of New Jersey. They closely follow the format of the federal administrative publications except that the NJR is published once every 2 weeks and the code in print is a looseleaf service update monthly incorporating all changes adopted in NJR. LexisNexis is the official publisher and obligated to provide a free online version to the public.

**New Jersey Administrative Code**
http://www.lexisnexis.com/hottopics/njcode/

**New Jersey Register** (from July 1995 on) at
http://www.lexisnexis.com/njoal.

The **New Jersey Register** from the first issue (September 25, 1969) through June 1995 can be accessed through the New Jersey State Library at
http://www.njstatelib.org/slic home/law library/new jersey legal resources/new jersey register

# Law Library

*Law Library of the New Jersey State Library*

**Local navigation**

- New Jersey Legislative Histories
- New Jersey Legal Resources
  - Administrative Law
  - Constitutions
  - Court Opinions
  - Executive Branch Materials
  - Forms
  - Judiciary Materials
  - Laws and Legislative Materials
  - Legal Periodicals
  - Local Ordinances
  - Miscellaneous
  - New Jersey Register
  - Old New Jersey Model Criminal Jury Charges
  - School Law Decisions
- Federal Legal Resources
- Historical Laws

**NJSL navigation**

- New Jersey State Library home (NJSL)
- Broadband Technology Opportunities Program (BTOP)
- Innovation and Outreach
- Law Library
- Library Support Services (LSS)
- Lifelong Learning (LLL)
- Marketing
- State Library Information Center (SLIC)
- Talking Book and Braille Center (TBBC)



## New Jersey Register

*in:* Law Library

A digitized collection of the New Jersey Register volumes from the first volume issued in 1969, through volume number 27, issued in 1995. Volume 27, Number 13, to the most recent volume are available via LexisNexis

| Volume 1 (1969) |
|---|
| Number 1, Pages 1–8 |
| Number 2, Pages 9–16 |
| Number 3, Pages 17–24 |
| Number 4, Pages 25–32 |
| **Volume 2 (1970)** |
| Number 1, Pages 1–8 |
| Number 2, Pages 9–20 |
| Number 3, Pages 21–28 |
| Number 4, Pages 29–36 |
| Number 5, Pages 37–44 |
| Number 6, Pages 45–52 |
| Number 7, Pages 53–60 |
| Number 8, Pages 61–68 |
| Number 9, Pages 69–80 |
| Number 10, Pages 81–88 |
| Number 11, Pages 89–96 |

**Search**

Choose where to search

enter search term(s)

Search now

**Latest News**

- Great Books Provide an Escape from Winter
- Raspberry Pi: The Raspbian ("wheezy") Operating System
- An Astronaut's Guide to Life on Earth by Col. Chris Hadfield

More news...

**Upcoming Events**

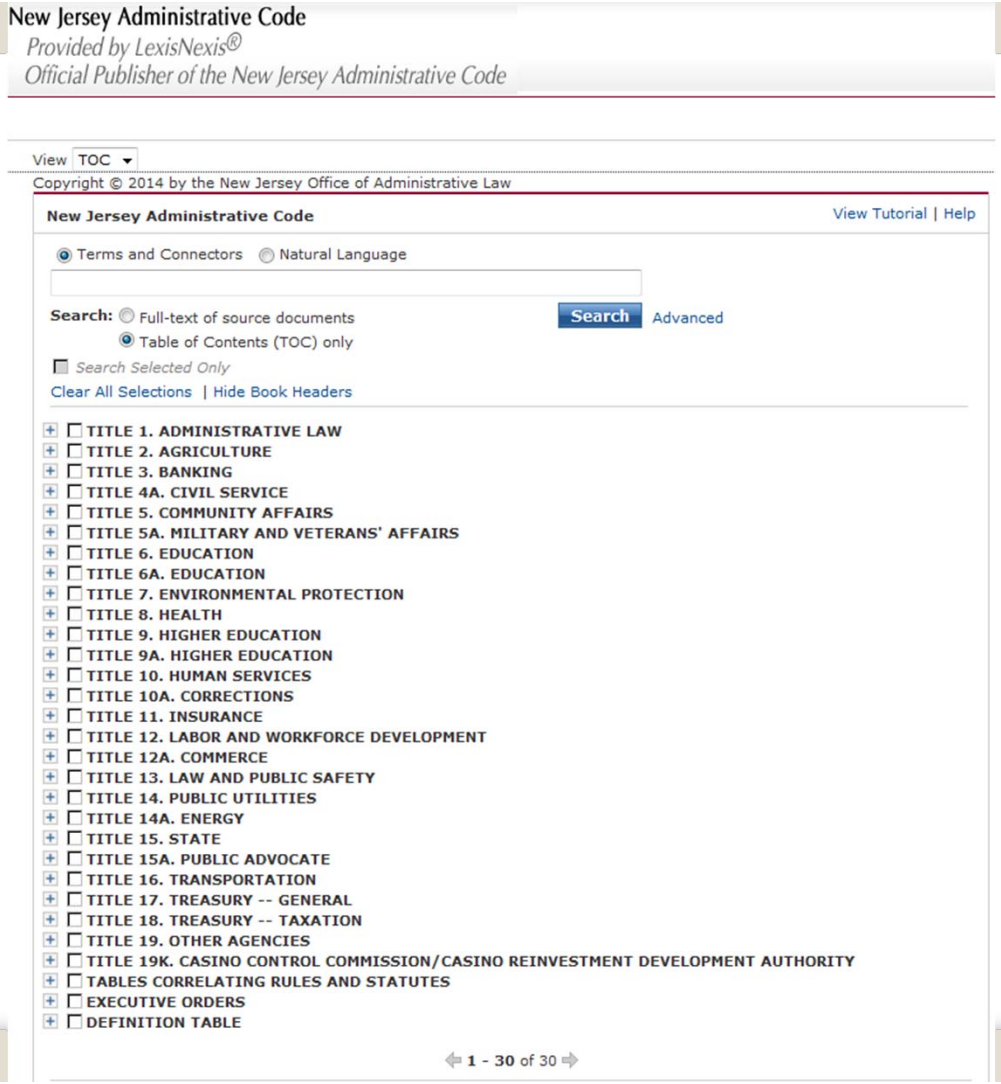
- State offices will be closed on Monday, March 3rd, due to inclement weather.
- Book Cafe on March 11, 2014
- 3-12-Sending a shamrock to remind you of home-author talk

More events...

**Lunchtime Learning**

- Hands-on Raspberry Pi 3: Setting up a Home Theater
- You Don't Know Google Maps
- Genealogy 3: Locating Vital

# N.J.A.C.


New Jersey Administrative Code
Provided by LexisNexis®
Official Publisher of the New Jersey Administrative Code
View TOC
Copyright © 2014 by the New Jersey Office of Administrative Law
New Jersey Administrative Code
View Tutorial | Help
Terms and Connectors
Natural Language
Search:
Full-text of source documents
Table of Contents (TOC) only
Search
Advanced
Search Selected Only
Clear All Selections | Hide Book Headers
TITLE 1. ADMINISTRATIVE LAW
TITLE 2. AGRICULTURE
TITLE 3. BANKING
TITLE 4A. CIVIL SERVICE
TITLE 5. COMMUNITY AFFAIRS
TITLE 5A. MILITARY AND VETERANS' AFFAIRS
TITLE 6. EDUCATION
TITLE 6A. EDUCATION
TITLE 7. ENVIRONMENTAL PROTECTION
TITLE 8. HEALTH
TITLE 9. HIGHER EDUCATION
TITLE 9A. HIGHER EDUCATION
TITLE 10. HUMAN SERVICES
TITLE 10A. CORRECTIONS
TITLE 11. INSURANCE
TITLE 12. LABOR AND WORKFORCE DEVELOPMENT
TITLE 12A. COMMERCE
TITLE 13. LAW AND PUBLIC SAFETY
TITLE 14. PUBLIC UTILITIES
TITLE 14A. ENERGY
TITLE 15. STATE
TITLE 15A. PUBLIC ADVOCATE
TITLE 16. TRANSPORTATION
TITLE 17. TREASURY -- GENERAL
TITLE 18. TREASURY -- TAXATION
TITLE 19. OTHER AGENCIES
TITLE 19K. CASINO CONTROL COMMISSION/CASINO REINVESTMENT DEVELOPMENT AUTHORITY
TABLES CORRELATING RULES AND STATUTES
EXECUTIVE ORDERS
DEFINITION TABLE
1 - 30 of 30

STATE OF NEW JERSEY
# OFFICE OF ADMINISTRATIVE LAW

Home | OAL | Rules | Contact & Directions | Hearings | Representation | Civil Service Hearings | Site Map

## QUICK LINKS

- OAL Decisions (1997-Present)
- OAL Decisions (1979-1991)
- Hearing Rules (*N.J.A.C.* 1:1-1 to 21)
- Rulemaking Rules (*N.J.A.C.* 1:30)
- New Jersey Register
- OAL Rule Proposals
- OPRA Instructions
- OPRA Request Form [.doc 75kB]

## ANNOUNCEMENTS

Click on the link below for Inclement Weather Information

Inclement Weather Information




## OAL MISSION

The Office of Administrative Law provides the citizens of New Jersey with a forum for the fair and impartial resolution of contested cases by independent administrative law judges who conduct hearings and render initial decisions.

The Division of Administrative Rules within the Office of Administrative Law oversees the publication of all State agency rule proposals and adoptions in the New Jersey Register and of all rule adoptions in the New Jersey Administrative Code.

OPRA | Open Public Records Act

Privacy Notice | Legal Statement & Disclaimers | Accessibility Statement

**--Each state has a similar system of publishing rules/regulations of its executive agencies, departments or commissions of government.**

**--To find out either go to that state's website or look it up in one of the online services (Lexis, Westlaw, Bloomberg Law or other.**

## CHECKLIST FOR CURRENT FEDERAL REGULATIONS

**Where found:** **Code of Federal Regulations (CFR)**

| | | |
|---|---|---|
| Access: | 1. | General index to set |
| | 2. | Privately published index by CIS |
| | 3. | Table of authorities cites from USC to regulations issued under statute |
| | 4. | Reference to regulation in court case, journal article, loose-leaf service, book, etc. |
| | 5. | Lexis or Westlaw |
| | 6. | Use GPO FDSys to search CFR: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR |
| Update: | 1. | List of Sections Affected (LSA) locates new regulations by table showing cite of regulations in Federal Register that affects CFR section. |
| | 2. | Latest issue of Federal Register for the month has a list of sections affected during that month |
| | 3. | Lexis or Westlaw |
| | 4. | Internet for Federal Register on FDSys: http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR |
| | 5. | Contact the agency or check the website for additional information |
| Extension: | 1. | Shepard's Code of Federal Regulations Citations(Lexis) or KeyCite(WestLaw) give court cases and administrative decisions citing the CFR. |
| | 2. | Cite in Federal Register where regulation is adopted gives background and reasons for adoption |

## CHECKLIST FOR CURRENT NEW JERSEY REGULATIONS

**Where found:** **New Jersey Administrative Code (NJAC)**

| | | |
|---|---|---|
| Access: | 1. | General index to set |
| | 2. | Individual title subject index |
| | 3. | Cross reference table from NJSA to NJAC for regulations issued under statute |
| | 4. | Internet - free access to NJ Administrative Code - http://www.lexisnexis.com/hottopics/njcode/ |
| | 5. | Lexis or Westlaw |
| Update: | 1. | New Jersey Register for new regulations. Use Index to Rule Proposals and Adoptions for regulations affecting NJAC cite |
| | 2. | Lexis or Westlaw |
| | 3. | Internet - free access to NJ Register - http://www.lexisnexis.com/njoal/ |
| | 4. | Contact the agency or check the web site for additional information on recent or proposed regulatory changes |
| Extension: | 1. | NJAC gives references to court cases discussing various sections of the regulation |
| | 2. | New Jersey Administrative Reports 2d (NJAR) has table of statutes and regulations cited by agency decisions (ceased publication in 1997); NJAR First Series is available on the Internet at http://njlegallib.rutgers.edu/njar/njarhome.htm;NJAR 3d is available on the Internet at http://lawlibrary.rutgers.edu/oal/search.html |
| | 3. | Original publication in New Jersey Register gives background and reasons for adoption. |

# The End

# Questions?

Consult your friendly law librarian!

Dianne Oster
(973) 642-8195
Dianne.oster@shu.edu