
INDEX

A

- Abbreviations, use of, 71, 72–75, 79
- Absolute risk, distinguishing, from relative risk, 143
- Academy of Pediatrics, 152–153
- Accelerated waivers, 197
- Accidents, states referring to reporting of, 117
- Accountability, 2, 7–8, 9, 12, 241
- Accreditation Association for Ambulatory Health Care (AAAHC), 224
- Accreditation committee minutes and agendas, 185
- Accreditation organizations. *See specific organizations*
- Accreditation process, confidentiality of information from, 189
- Accreditation status, 27, 36
- Accreditation surveys, 37, 188
- Accreditation watch, at risk for being placed on, 188
- Action plans: charting, 126; confidentiality of, 189; identifying, 125; implementing and reviewing, 188
- Acute renal failure, 88
- Adams, A. M., 142, 157
- Adams, R. K., 160
- Administering medication, 70, 75, 81–82
- Admissibility, rules of, continued testing of, 29. *See also Confidentiality; Evidentiary protection*
- Advance planning of disclosure conversations, 155
- Adverse drug events (ADEs): analysis involving, 52, 53; claims triggered by, percentage of, 84; and newly approved drugs, 87–88; preventable, percentage of claims deemed as, 183; reduction in preventable, 70, 76; reporting, 119–120, 179, 208. *See also Medication errors*
- Adverse event, definition of, issues with, 6, 14, 106, 172
- Adverse event reporting. *See Reporting entries*
- Adverse events: precursors of, 19; proactive steps to managing, 108–117; responding to, in research settings, 168–178; states referring to reporting of, 117, 186. *See also specific type*
- Adverse Health Care Events Reporting Law, 14n5
- Adverse reactions: differentiating, 167; educating research participants on, 163; reporting requirement for, 120, 209. *See also Adverse drug events (ADEs)*
- Affirmation statement, 190
- Agency for Health Care Administration, 186
- Agency for Healthcare Research and Quality (AHRQ), 42, 44, 65, 71, 76, 93, 209
- Aircraft design, 46–48
- Alabama laws and regulations, 123n8, 190, 191, 192, 198, 202
- Alarm systems, clinical, improving effectiveness of, 28, 66
- Alaska laws and regulations, 192, 198, 202
- Alcoholics Anonymous (AA) meetings, 221
- Alcoholism patients, 214
- Algorithms, use of, 167, 171

- Allergic reactions, 84
- Ambulatory care organizations,
patient safety standards for,
setting, 36, 187
- Ambulatory care units, signage
at, 164
- Ambulatory surgical facilities, 20
- Amente v. Newman, 195–196,
196–197, 217
- American Academy of
Pediatrics, 157
- American Board of
Anesthesiology, 227
- American Board of General
Surgery, 227
- American Board of Internal
Medicine, 227
- American Board of Medical
Specialties (ABMS), 225,
227, 233
- American Board of Obstetrics and
Gynecology, 227
- American Board of Pediatrics, 227
- American College of Obstetricians
and Gynecologists (ACOG), 29,
152, 157
- American College of Physicians,
152, 157
- American Dental Association, 225
- American Hospital Association
(AHA), 85
- American Jurisprudence*, 194, 217
- American Medical Association
(AMA), 85, 152, 157
- American Medical Systems, York v.,
207–208, 218
- American Nursing Association
(ANA), 85
- American Osteopathic Association
(AOA), 34, 39, 225, 228, 233
- American Podiatric Association, 235
- American Society for Healthcare
Risk Management (ASHRM),
85, 85–86, 108, 109, 123,
153, 157
- American Society for Quality
(ASQ), 41
- American Society of
Anesthesiologists (ASA),
29, 35, 44
- American Society of Health-System
Pharmacists (ASHP), 86
- Amniocentesis risk, patient decision
making about, example of,
146–147
- Analyses, types of, 69. *See also*
specific type
- Analysts: discretion of, 56; role
of, 62
- Anecdotal risk descriptions,
avoiding, 149
- Anger, dealing with, in patients,
155–156
- Anonymous reporting, 67, 121, 134
- Antibiotics, 83
- Anticoagulants, 83
- Antihypertensives, 84
- Apology, 14n2, 152
- Applicable standard, proving, 11
- Arizona laws and regulations,
122n7, 123n9, 192, 198, 202
- Arkansas laws and regulations,
122n7, 123n17, 192, 195,
198, 202
- Association for Professionals in
Infection Control and
Epidemiology, 35
- AT&T, United States v., 183, 218
- At-risk individuals, 162
- Attorney-client privilege, 125, 129,
183, 217
- Attorney-work product
privilege, 183
- Audience-seeking behavior, 134
- Australia, 35, 41
- Authority levels, extension of, 132
- Automated dispensing device, 80
- ## B
- Babcock v. Bridgeport Hospital,
201, 217
- Background information,
importance of, 165–166,
177–178
- Bagian, J. P., xiv
- Bar Code Administration Project
(BCAP), 81
- Bar-coding system, computerized,
incorporating, 81, 91
- Barriers, 6, 20, 105, 183
- Baseline risk, describing, 144
- “Basic Standards for Preanesthesia
Care,” 35
- Bates, D. W., 70, 75, 76, 93
- Beck v. Bluestein, 200, 217
- Becker, C., 81, 93
- Beckman, H. B., 89, 93, 149, 150,
157, 158
- Behavioral care facilities: patient
safety standards for, setting, 36,
187; reporting required, 20
- Bell, P.R.F., 142, 144, 148, 158
- Belmont Report, 160
- Benchmark data, use of, 96,
98–102
- Benchmark report card, 102
- Benchmarking, definition of, 97
- Benchmarks: for evaluating law
firms, 130; for hospitals, 38; for
physicians, 230; setting, use of
evidence-based outcome data
for, 97–98
- Benjamin, D. M., 64, 70, 83, 84, 85,
86, 88, 92, 93, 95
- Berger v. Lutheran General
Hospital, 196, 217
- Best practices, sharing, system for,
as prerequisite, 102
- Beyth-Marom, R., 143, 157
- Bilirakis, M., 92
- Bill abatement, 112, 138
- Billing analysis, 126, 127–128
- Biological Product Deviation
Reporting (BPDR), 208
- Biologics, reporting events
associated with, 179, 208
- Biomedical engineering
department, notifying,
111, 119
- Biomedical engineering firm,
involving, in examination
of devices, 170
- Biostatistician, need for, 180
- Bioterrorism, 31
- Birth defects or birth with
disease, reporting requirement
for, 120
- Birthing centers, 20
- Blame: avoiding, 106, 153, 156;
corrective action versus,
232–233; moving away from,
7–8, 87, 90, 105, 232; open
invitation to, 18, 138
- Blendon, R. J., 89, 93
- Blind clinical studies, 181

- Bluestein, Beck v., 200, 217
 Board of Psychology Examiners, McMaster v., 196, 218
 Booth, M., 18, 33, 184, 218
Boston Globe, 70
 Braddock, C. H., 150, 157
 Breaux, J., 92
 Brennan, T., 17, 33, 105, 123
 Bridgeport Hospital, Babcock v., 201, 217
 Brigham and Women's Hospital, 144
 Brown, D., 90, 94
 Bryan, P., 19, 33
 Bryson, Nielson v., 197, 218
 Burnout, 221
 Business case, seeking a, 68, 99
 Buyers Health Care Action Group, 99
- C**
- California Business & Professions Act, 14n3, 37
California Health Safety Code, 14n3, 37
 California laws and regulations, 2, 12, 14n3, 17, 32n2, 37, 122n7, 123n13, 17, 153, 192, 198, 202
 California Medical Board, 229
 Call centers, staffed, providing, 177
 Calman, K. C., 143, 157
 Cannistra, J., 81, 94
 Cardiem, 91
 Cardizem, 91
 Career transition, 227
 Caregivers. *See specific type*
 Catastrophic event, meaning of, 49
 Celebrex, 91
 Celexa, 91
 Center for Biologics Evaluation and Research (CBER), 208
 Center for Devices and Radiological Health (CDRH), 207, 208
 Center for Drug Evaluation and Research (CDER), 208
 Center for Food Safety and Applied Nutrition (CFSAN), 208
 Center for Medicaid and State Operations/Survey and Certification Group, 233
 Center for Personalized Education for Physicians (CPEP), 227, 233
 Center for Quality Improvement and Patient Safety, 23
 Center for the Advancement of Patient Safety, 95
 Centers for Disease Control and Prevention (CDC), 31, 206–207, 209, 217
 Centers for Medicare & Medicaid Services (CMS), 16, 29–30, 36, 39, 41, 96, 98, 101, 102, 209, 233
 Cerebryx, 91
 Certification, 36, 224, 225
 Chain of command, 128, 240
 Change, need for, 241
 Chat rooms, 164
 Checklists, use of, 163
 Chemotherapy overdose, 70
 Chestnut Lodge, Inc., Kappas v., 201, 218
 Chicago Trust Co. v. Cook County Hospital, 201, 217
 Children's hospitals, communicating with parents at, 139
 Chopra, S., 150, 157
 Cidofovir, 31
 Citizen Advocacy Center, 229, 233
 Claim information, managing, 133
 Claim settlements, size of, and full disclosure, 154
 Claim triggers, types of medication errors as, 84
 Claims management: outsourcing, 107; perspective of, 53
 Claims paid, focusing analysis on, methods for, 54, 55
 Claims strategies, effects of disclosure on, 136–139
 Clarification, seeking, 90
 Classen, D. C., 76, 94
 Clayton, E. W., 152, 158
 Clinical alarm systems, improving effectiveness of, 28, 66
 Clinical care team, having a procedure for notifying, 167
 Clinical conditions, consideration of, 86
 Clinical contingency plan, 167–168
 Clinical knowledge, updating, assistance in addressing, 227
 Clinical management algorithms, having, 167
 Clinical pathways, and standards of care, 9–10, 11, 42
 Clinical pharmacists, increasing use of, 70
 Clinical practice, absence from, physicians returning after, 227
 Clinical practice guidelines, and standards of care, 9–10, 11, 42
 Clinical privileges, 222, 228, 231
 Clinical response monitoring, 82
 Clinical rules: built into computer system, 80; for computer entry, careful construction of, 79
 Clinical trials: adverse-event reporting in, 26–27, 172–175; creating a safe environment for, 162–167. *See also Research entries*
 Closed ICUs, 228
 Closure, achieving, 135
 Cochran v. St. Paul Fire and Marine Insurance Co., 195, 196–197, 217
Code of Medical Ethics (AMA), 152
Code of Professional Ethics (ACOG), 152
Code of Professional Ethics and Conduct (ASHRM), 153
 Cohoon, B. D., 82, 94
 Coiera, E., 71, 94
 Collective bargaining agreements, 223
 Collegial approach, 232
 Colorado Department of Public Health and Environment, 185
 Colorado laws and regulations, 2, 14n2, 20, 32n2, 122n3, 7, 123n16, 17, 153, 184, 185, 192, 198, 202
 Colorado Nursing Board, 229
 Commercially insured institutions, 107, 108, 112
 Commercially prepared solutions, use of, 80
 Commission on Accreditation of Rehabilitation Facilities (CARF), 34
 Commissions, delineating omissions and, in medical errors, 3
 Committee meetings. *See specific committees*
 Committee on Bioethics, 157
 Common law protection, 210, 216–217

- Common Rule, 160, 174
- Communicating about events:
 - proactive steps in, 112–113; in research settings, 171–178;
 - responsibility for, addressing, 112, 136, 137. *See also Disclosure entries; Reporting entries*
- Communicating risk, 141–145
- Communication: computational, 71; ex parte, 196; failures of, resulting in lawsuits, 89–90, 152; importance of, 175; improving effectiveness of, 27, 66, 132; with law firms, extensive, 132; privileged, protecting, 210; strategies of, used by providers, issues with, 149–152; between team members, 240
- Communication imbalance, 137
- Communication patterns, 71
- Communication safety net, 165
- Communication selections, 71
- Communication skills, learning, 141
- Communication tool, consent process as a, 162, 163
- Communication-related errors, 70–71
- Community Health Accreditation Program (CHAP), 34
- Community Hospital of Indianapolis v. Medtronic, 201, 217
- Comparable standards, using, 10
- Compensation, fair, for families, 154
- Competency-based testing, using, 13
- Complex legal risk exposure, dealing with, 134–136
- Complexity: of informed consent forms, 148–149; of modern health care, 64, 71
- Compliance information, confidentiality of, 189
- Computational communication, 71
- Computer entry errors, 76–79
- Computerized bar codes, incorporating, 81, 91
- Computerized physician order entry (CPOE), 39, 40, 70, 75–78, 85, 90, 99
- Concentrated potassium chloride (KCl), 64–65, 83
- Concomitant use, reducing, 87
- Conditions of Participation (CoP) in Medicare and Medicaid, 12, 16, 29–31, 35, 36, 173, 175
- Confidentiality: in claims management, 133; in the face of litigation, protections for, 183–217; federal legislation on, 23, 24; inconsistent legal requirements for, 5–6; in investigative interviews and reviews, 111, 113; lack of, concerns over, 18; and malpractice cases, 19; in medical device reporting, 25–26, 119, 170; in medication error reporting, 67, 121; proactive strategies for, 114–117; using MedWatch, 120. *See also Evidentiary protection; Protection legislation*
- Confidentiality agreement, 170
- Conflict of interest, addressing, 135
- Connecticut laws and regulations, 32n2, 40, 116–117, 122n7, 123n13, 192, 194, 198, 202
- Consent document, 164, 177
- Consent tools, employing, for research participants, 162–163
- Consent to release protected health information, 214
- Consent to treatment. *See* Informed consent
- Consequential thinking, involvement of, in analysis, 50–62
- Consistent approach, following, 13
- Constitutional right to privacy, 195, 196
- Consumers: reporting quality data to, issue of, 98; use of benchmark data by, 101–102
- Context: issue of, in use of terminology and data, 3, 4; standards applied in, importance of, 11
- Contingency plan, clinical, 167–168
- Continuing education, importance of, 90
- Continuous quality assurance, in human research, 167
- Continuous quality improvement, approach to, 35
- Continuum of care, 2, 13–14, 229
- Contradictory reports, issue of, 174, 175
- Contraindicated drugs, giving, 84–85
- Contraindications, ruling out, 86
- Control charts, 41, 100
- Conversational communication, 71
- Cook County Hospital, Chicago Trust Co. v., 201, 217
- Cookbook clinical research, 163
- Cookbook medicine, 100
- Coombs, R. H., 150, 157
- Copies: making, 132, 169; redacted, 195–196, 207, 212; shredding, 189
- Coroners, 112, 125, 168
- Corporate accountability, 231
- Corporate counsel, retaining separate, 135
- Corporate liability, 231
- Corporate negligence, 19
- Corrective action: versus blame, 232–233; and data sharing, concerns surrounding, addressing, 7–8; evaluating need for, 107
- Corrigan, J. M., 1, 15, 16, 17, 33, 34, 44, 91, 94, 117, 123, 232, 234
- Corrigan v. Methodist Hospital, 200, 217
- Cost containment, full disclosure and, 154
- Costs: addressing, in medication safety initiatives, 69, 70; of adverse drug events, 76; concerns over, physician emphasis on, 89; of preventable medication errors, 93
- Cost-saving measures, issues concerning, 61–62
- Council on Ethical and Judicial Affairs, 157
- Counsel, legal. *See* Legal counsel
- Counseling: professional, 221, 222; risk, offering, 148–149
- Court orders, 113, 116, 122, 191, 207, 211, 213, 214
- Cousins, D. D., 65, 67, 71, 79, 80, 81, 82, 83, 94, 95

- Coverage, determining, of laws and regulations, 20
- Covered entities under HIPAA, 214
- Credentialing process, 223–232
- Credibility with jurors, 138
- Criminal background checks, 231
- Critical care subspecialty certification, 227–228
- Criticality rating, 47, 53
- Crofton, J., 145, 157
- Crossing the Quality Chasm: A New Health System for the 21st Century* (Institute of Medicine), 16, 232
- Cultural differences, between industry and health care, accounting for, 45, 48, 51, 52
- Culture: of openness, establishing, 79; of safety, developing, 85, 87, 232. *See also* Organizational culture
- D**
- Dana Farber Cancer Institute, 8
- Data. *See specific type*
- Data analysis: biostatistician needed for, 180; in medication safety initiative model, 69
- Data and safety monitoring boards (DSMBs), 161, 178–181
- Data capture: identifying reportable events for, 105–106; inadequate or inconsistent, issue of, 67
- Data collection: coordinating and integrating, 209; limited, reasons for, 60; in medication safety initiative model, 69
- Data comparison, difficulty with, 21
- Data confidentiality. *See* Confidentiality
- Data, deidentified. *See* Deidentified information
- Data fields, allocating ample space in, 78
- Data impact, 69
- Data management, addressing, 132–133
- Data monitoring committees (DMCs). *See* Data and safety monitoring boards (DSMBs)
- Data sets, standardized, need for development of, 2, 3–4. *See also* Standardization
- Data use, issues concerning, 19
- Daubert v. Merrell Dow Pharmaceuticals, Inc., 29, 32
- Davenport, Kutner v., 200, 218
- DEA certificate, 224
- Death, medical error as a leading cause of, 1, 117
- Death rates. *See* Mortality rates
- Deaths, reporting of: determining need for, and extent of, 125, 127; guidance on, 112; from medical devices, requiring, 25, 118; states referring to, 117
- Decertification, 43
- Decision boards, use of, 148
- Decision making, patient, 146–148
- Decision trees, completing, 148
- Declaration of Helsinki, The, 160
- Deemed status, meaning of, 36, 42
- Defense standardization, 130
- Defense strategies: coordinated, 134–136; maintaining consistency in, 125
- Definitions: standardized, use of, 207; uniform, example of, 118; universal, need for, 6, 14; varied, awareness of, 20–21, 106, 172. *See also* Terminology
- Deidentified information, 23, 67, 214, 215. *See also* Redacted copies
- Delaware laws and regulations, 122*n*4, 192, 198, 202
- Demonstration projects, support for, 209
- Demotion, 222
- Dentists, 195
- Department chairs, 238
- Department of Health and Human Services, Roberts v., 212, 218
- Department of the Air Force, Painting Industry of Hawaii v., 213
- Dependency role, 148
- DeRosier, J., xiv
- Detroit Osteopathic Hospital Corp., Dorris v., 201, 218
- Deviation in manufacturing, defining, 208
- Devices, medical. *See* Medical devices
- Dieticians, 237
- Diette, G. B., 98, 103
- Diltiazem, 83
- Disability, reporting requirement for, 120
- Disagreement, productive, 240
- Disciplinary actions, 7–9, 18, 186, 222–223. *See also* Corrective action
- Disciplinary hearings, right to, 223
- Disclosure: benefits of, 156–157; communication issues in, 112–113; during consent process, 162; effects of, on claims strategies and litigation, 136–139; managing, principles of, 153–154; premature, pressure to make, 180; professional rules and standards for, 152–153; of research-related adverse events, 175–176; states requiring, 14*n*1, 22–23; strategies for, 154–156
- Disclosure conversations, principles for conducting, 154–155
- Disclosure policies or guidelines, having, in place, 109, 136–137, 139, 153
- Disclosure shields. *See* Protection legislation
- Discovery, protection from. *See* Evidentiary protection
- Disease testing for prospective employees and staff, 231
- Disparate standards, content of, evidence-based, 12
- Dispensing errors, 75, 80–81, 84, 90–91
- Dispensing medication, 70, 80
- Dissemination, in medication safety initiative model, 69
- Distractions, 85
- District of Columbia District Court, 195
- District of Columbia laws and regulations, 117, 184, 192, 195, 198, 202
- Distrust: of benchmark data, 100; public, of providers, 104; of reporting systems, 18

- Document management system, 130, 133
- Documentation: in administering and monitoring medication, 81; of disclosure, 137, 156; of interviews, 170; in medical device reporting, requirements for, 25; of risk counseling discussion, 149; sequestering of, 169; of standards or processes, 13. *See also* Incident reports; Medical records
- Doe v. Stephens, 211, 217
- Dollar values, attaching, 60, 61, 76, 107
- Donabedian, A., 97, 102
- Donaldson, M. S., 1, 15, 16, 17, 33, 34, 44, 91, 94, 117, 123, 232, 234
- Dopamine, 83
- Dorris v. Detroit Osteopathic Hospital Corp., 201, 218
- Dosage units, standard abbreviations for, using, 79
- Dosing errors, 77, 78, 84, 90–91
- Dosing protocols, standardized, 78
- “Dr. Death,” 230
- Drug abuse patients, 214
- Drug abuse prevention and control research participants, protecting identity of, 213–214
- Drug applications, new, requirements for, 26
- Drug delivery modes, various, 80
- Drug Enforcement Administration (DEA), 224
- Drug information, lack of, addressing, 90
- Drug labels, 88, 209, 238. *See also* Medication labels
- Drug market, withdrawal from, 84–85
- Drug names, similar, problem of, 65, 71, 77, 90, 91
- Drug-drug interactions, 84–85, 86, 88
- Drug-related events. *See* Adverse drug events (ADEs)
- Drugs, high-alert. *See* High-alert medications
- ## E
- Early injury review, 153
- Early warning systems, 18, 25, 237
- ECRI, 24, 25, 32, 32n3,4, 71, 94, 111
- Education: about seeking emergency treatment, 177–178; in communication skills, 141; consumer, means of, 102; continuing, importance of, 90; for everyone involved in clinical trials, 166; importance of, in using medication equipment, 85; of involved staff following an event, 135; leadership, need for, 241; professional, 227, 229; public and media, importance of, 4; of research participants, 162–163, 166, 177–178, 209; on standards and processes, 13
- Effects analysis, failure modes and. *See* Failure modes and effects analysis (FMEA)
- 80/20 rule (Pareto Principle), 50, 51, 56, 58
- Ekstrom v. Temple, 201, 218
- Electrolytes, 83
- Electronic communications, 132
- Electronic medical records (EMRs), 70, 90
- Electronic prescription submission, 79
- Electronic record data, making verified copies of, 169
- Elements of performance (EPs), 38
- Elkadry, E., 145, 157
- Ellis, D. A., 145, 157
- E-mail contact information, providing, 166, 178
- E-mail message systems, 164, 177
- E-mail monitors, providing instruction sheets to, 168
- Emergency Care Research Institute. *See* ECRI
- Emergency Medical Treatment and Labor Act (EMTALA), 135
- Emergency situations, waiver of consent in, 179, 214
- Emergency treatment, seeking, for adverse events, educating participants about, 177–178
- Empathy, showing, importance of, 155
- Employee assistance program (EAP), 134, 221–222, 231
- Employee benefits reduction, 222
- Employee grievance procedures, 223
- Employment and disciplinary issues, addressing, 219–223
- Enforcement authority, determining, 21
- Enforcement, increase in, 20
- Engineering characteristics, 45, 52
- Enoxaparin, 83
- Enrollment, providing instructions sheets at time of, 168
- Environment of care safety, focusing on, 40
- Epstein, R. M., 150, 158
- Equipment, medical. *See* Medical device entries
- Error, universal definition of, need for, 14
- Errors. *See* specific type
- Ethical obligation, 152, 153
- “Ethics and the Care of Critically Ill Infants and Children” policy statement, 152–153
- Ethics Manual* (American College of Physicians), 152
- Ethics personnel, contacting, offering means of, 134
- Evaluating events, 107. *See also* Expert reviews
- Evidence for standards compliance (ESC) report, 27
- Evidence-based hospital referral (EHR), 39, 40
- Evidence-based outcome data, use of, for benchmarking, 97–98, 101
- Evidence-based recommendations, 37–38
- Evidence-based standards, 12, 17, 29, 42, 96, 100
- Evidentiary protection: concerns surrounding, addressing, 5, 6–7; determining, 170; at the federal level, 206–217; need for, reaching a balance between, and patient safety promotion, 122; of periodic performance reports,

- 38; redesigning laws that address, consideration of, 2, 7; at the state level, 184–206. *See also* Confidentiality; Protection legislation
- Ex parte communication, 196
- Excess insurance carriers, notifying, 112
- Executive committees, protection of, 200
- Executive leadership. *See Leadership entries*
- Expectations: setting reasonable, 13; surrounding specialists, 10, 11
- Expert reviews, 111–112, 113. *See also Peer review entries*
- Expert-based recommendations, 37–38
- Extended family, including, in disclosure conversations, 156
- Extended length of stay, analysis involving, 53, 56
- External benchmarking, defined, 97
- External data, analyzing, 178
- F**
- Fact finding, multiple layers of, dealing with, 134, 175
- Factual disclosure, importance of, 137, 155
- Factual reports, importance of, 106
- Fail-safes, 169, 241
- Failure analysis, warranting of, 167. *See also* Root cause analysis (RCA)
- Failure, meanings of, 52
- Failure modes and effects analysis (FMEA): applying, to health care, 48–50; connotations of, consideration of, 45, 51–52; and consequential thinking, 50–62; for medication error reduction, 78; traditional roots of, 46–48; using, 13, 41
- Failure modes, effects, and criticality analysis (FMECA), 51, 52, 60. *See also* Opportunity analysis
- Failure tree analysis (FTA), 51, 52, 60
- Fair compensation, for families, 154
- False sense of security, creating a, 177
- False-alarm fatigue, reducing, 79
- Family members: fair compensation for, 154; including, in disclosure conversations, 112–113, 163, 175–176; involvement of, in consent process, 156; system requiring notification of, 22–23; valuable role of, recognizing, 235; working to better inform, 241
- Fault tree analysis (FTA), 51, 52, 60
- FEARED approach, 155–156
- Fears, awareness of, that constrain patient safety, 6–9
- Federal agency, new, establishment of, calls for, 17. *See also specific federal agencies*
- Federal funding, increase in, 104
- Federal laws and regulations: absence of, on maintaining confidentiality, 6, 18; changes in, and reporting matrices, 173; on the horizon, 122; on human research, 160, 174; on medical devices, 207; and medication error reduction, 91–92; providing evidentiary protection, 210–216; on reporting, 23–24; on reporting process, 118–120; versus state rules, 20. *See also specific laws and regulatory agencies*
- Federal Rules of Civil Procedure (FRCP), 183, 210–211
- Federal Rules of Evidence, 210, 216, 217
- Federal standards, 12
- Feedback, 85, 97, 98, 130, 133, 134, 209
- Fellows, supervision of, 230–231
- Fentanyl, 83
- Fetal monitoring strips, 109, 110, 113
- Fibrinolytics, 84
- Field-testing, 13, 102
- Final analysis, 175
- Fines, 22
- Five rights, the, 91
- Five wrongs, the, 84
- Florida laws and regulations, 2, 14n1, 32n2, 122n5, 7, 123n14, 153, 184, 186, 192, 194, 198, 202
- Florida Supreme Court, 195
- Flowcharts, constructing, 171
- Flowers, K., 150, 158
- Flowers, L., 2, 14, 18, 33
- Following-up, 168
- Food and Drug Administration. *See* U.S. Food and Drug Administration
- Food, Drug, and Cosmetic Act, 213–214
- Ford Motor Company, 99
- Forum shopping, elimination of, 161
- 4PatientSafety.net, 229, 233
- Fox v. Kramer, 201, 218
- Framework for Conducting a Root Cause Analysis, 168
- Frankel, R. M., 89, 93, 149, 157
- Franklin Square Hospital, Timothy Laubach et al v., 110, 123
- Fraud and abuse, 127–128, 134
- Freedom of Information Act (FOIA), 119, 207, 211–213
- Freedom of information acts, state, 190–191, 192–194
- Free-flow errors, avoiding, 82
- Freestanding urgent care clinics, signage at, 164
- Frequency of occurrence data, 56
- Frequent occurrence, meaning of, 49
- Frequently asked questions (FAQs), using Web sites to address, 164
- Frist, B., 92
- Full disclosure, aspects of, 140–157
- Furosemide, 83
- Future errors, preventing, 23
- Future planning, aspects in, 235–241
- G**
- Gallagher, T. H., 152, 157
- Gawande, A. A., 144, 158
- Gelsinger, J., 26
- General life risks, 145, 146

- Generational factor in provider-patient communication, 140, 141
- Generic standards, 41
- Geneva, Switzerland, 40
- Georgia laws and regulations, 32*n*2, 122*n*7, 123*n*13, 184, 192, 194, 198, 202
- Gerberding, J., 209
- Gherman, R. B., 143, 158
- Giles, C. W., 219
- Ginsburg, P. B., 225, 233
- Githens, P. B., 152, 158
- Good catches, 2, 237–238
- Gorawara-Bhat, R., 150, 158
- Graduate education programs, standards for, 230
- Gray areas, 141
- Gregg, J., 92
- Grievances, 223
- Grimes, D. A., 144, 158
- Guessing, 90
- “Guidelines for Managing Risk in the Healthcare Sector,” 41
- ## H
- Hall, T.A.L., 149, 158
- Hamm, G., 153, 154, 158
- Handbook of Procedures for the Trial of Protracted Cases*, 211
- Hardin, S. B., 152, 159
- Harmful errors, capturing, 67, 68
- Harried professionals, 221
- Harvard Medical Practice Study, 89
- Hawaii laws and regulations, 122*n*1, 2, 190, 192, 198, 202
- Hayes, P. D., 142, 144, 148, 158
- Hazard reports, issuing, 24
- Hazard scoring matrix, 50
- Health care, aims of, 97
- Health care industry, changes in, 104
- Health care networks, patient safety standards for, setting, 187
- Health care quality. *See Quality entries*
- Health Care Quality Improvement Act (HCQIA), 197
- Health care system, design of, and error prevention, 64
- Health departments. *See State health departments; U.S. Department of Health and Human Services (HHS)*
- Health, Education, Labor, and Pensions (HELP) Committee, 92
- Health Insurance Portability and Accountability Act (HIPAA) regulations, 166, 176, 214
- Health Resources and Services Administration (HRSA), 229
- Healthcare Facilities Accreditation Program (HFAP), 34, 39
- Healthcare—acquired infections, reducing risk of, 28, 66
- Hearsay exception, 216
- Henkel, J., 209, 218
- Heparin, 83
- Hicks, R. W., 65, 67, 71, 79, 80, 81, 82, 83, 94, 95
- Hickson, G. B., 89, 94, 152, 158
- High-alert medications, 27, 66, 81, 82–85, 86
- High-intensity ICU staffing, 228
- High-risk neonatal care, performance-based rules for, calls for, 99
- High-risk process, determining, issue of, 52
- High-risk trials, 161, 178, 181
- High-volume referral, 39
- Hippocratic oath, 151
- Hismanyl, 85
- Historical data, use of, 54
- HIV patients, confidentiality of, 214
- HL7 Clinical Document Architecture format, 3
- Hoester, State ex rel. St. John’s Mercy Medical Center v., 200, 218
- Home care organizations, patient safety standards for, setting, 36, 187
- Homeland Security Act, 31
- Honest answers, offering, 156
- Honest input, no repercussions for, promise of, 238, 239
- Hopkin, J. M., 145, 157
- Hopper, K. D., 149, 158
- Hospital administration, notifying, 112
- Hospital licensing requirements, 187–188
- Hospital signage, 164
- Hospitalization, reporting requirement for, 120
- Howard, Payne v., 194–195, 218
- Human factors, in medication errors, 85
- Human failure and systems failure, 169
- Human research. *See Research entries*
- Hydromorphone, 83
- ## I
- “ICU Physician Staffing Factsheet,” 228
- ICU physician staffing (IPS), 39, 40, 99
- Idaho laws and regulations, 122*n*6, 192, 198, 202
- Identification numbers, 166, 177, 211
- Illinois laws and regulations, 192, 196, 198, 201, 203
- Immediate family, involvement of, in consent process, 163
- Immediate investigation, determining need for, 109
- Immunity, promise of, 238, 239
- Impaired performance, 221, 226, 231
- In re Krynecki, 216, 218
- Incident reporting process: legal and regulatory requirements guiding, 117–122; overview of, 105–107; steps in, 108–117
- Incident reports, 105, 106, 107, 115, 116, 133, 187, 201
- Incidents, states referring to reporting of, 21, 117, 187
- Indiana laws and regulations, 122–123*n*7, 123*n*10, 17, 192, 198, 203
- Individual-based accountability, approach premised on, 2, 7–8, 9
- Infection control committees, protection of, 201
- Infection control program, 100
- Infection control reporting system, 206–207

- Infections, health-care acquired, reducing risk of, 28
- Information confidentiality. *See* Confidentiality
- Information sets, standardized, need for development of, 2–4, 14. *See also* Standardization
- Information sharing: constraints on, 5–9; institutionalizing, 229
- Information sources, usefulness of, 18
- Information technology, expanding role of, 90
- Information users, internal, managing needs of, 132–133
- Informed consent: obtaining, 141, 160; process of, 145–152, 161, 162–163, 176; waived, 179
- Informed consent forms, 148–149
- Infrastructure failures, reporting, 21
- Infusion pumps, improving safety of, 28, 66, 81
- Infusion rate charts, preprinted and standardized, 81
- Infusion tubing, improving safety of, 82
- Initial appointment period, 224
- Innovation, enabling, 240
- Insignificant risk, determination of, 143
- Institute for Healthcare Improvement, 65
- Institute for Safe Medical Practices (ISMP), 85
- Institute of Medicine (IOM), 1, 2, 3, 14, 16, 17, 18, 19, 32, 34, 89, 91, 94, 97, 103, 117, 136, 161, 232, 233
- Institutional committee meetings, obtaining information from, 108
- Institutional medication error reduction, 70–88
- Institutional Review Boards: A Time for Reform* (U.S. Department of Health and Human Services), 161
- Institutional review boards (IRBs): improving function of, recommendations for, 161, 178–179; notifying, 167, 172, 173, 176, 180; relationship of data and safety monitoring boards to, 180–181; requirements for, 26, 174; responsibility of, 160, 178, 181
- Institutional settings, medication error reduction in, 70–88
- Institutionalizing information sharing, 229
- Instruction sheets, providing, 168, 177
- Insulin, 83, 84
- Insurance bills, abating, 112
- Insurance companies, blaming, 90
- Integrity, importance of, 9
- Intellectual property, protecting, 170
- Intensive care unit (ICU) physician staffing, 99, 227, 228
- Intensivists, increase in, 99, 228
- Interactive Web sites, use of, for research participants, 164
- Interim data, analyzing, 178, 179
- Intermediate scrutiny test, 216
- Internal benchmarking, defined, 97
- Internal information users, needs of, managing, 132–133
- Internal needs assessment, use of, in selecting outside legal counsel, 129
- Internal reporting process. *See* Incident reporting process
- International Classification of Diseases (ICD) 9/10-CM E-codes, 3
- International Organization for Standardization (ISO) approach, incorporating, 35, 40–41
- Internet reporting. *See* On-line reporting; Web-based reporting
- Interns, supervision of, 230
- Interpersonal care, complaints over, 89
- Interrupting patients, problem with, 149–150
- Intervention required to avoid permanent damage, reporting requirement for, 120
- Interventions, implementation of, as prerequisite, 102
- Interviews: investigation, 107, 110–111, 113, 170; with potential law firms, 131
- Invasion of privacy, unwarranted, determining, 212
- Investigating events: and disclosure, 154; involving human research, 168–169, 170–171, 173, 174, 175; processes in, 107, 109–112, 113, 114; and terminated or suspended employees, 220, 221
- Investigation summaries, protection of, 185
- Investigational medical devices, 169, 174
- Investigational new drug (IND) requirements, 26, 174
- Iowa laws and regulations, 122*n*1, 192, 196, 198, 203
- Iowa Supreme Court, 196
- ISO 9000 and ISO 1400, 41
- IV anticoagulants, 83
- IV infusions, 79, 80, 82, 85
- ## J
- Jaffee v. Redmond, 216–217, 218
- Jagodzinski, N. S., 46
- JAMA editorial, 64
- Japan, 32*n*1
- Jeffords, J., 92
- Job performance, substandard, addressing, 220–223, 226, 231
- Job reassignment, 220–221
- Job retraining, 222
- John C. Lincoln Hospital and Health Center v. Superior Court, 201, 218
- Johns Hopkins Medical Institutions, 228
- Johns Hopkins University, 238
- Johnson, N., 92
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 14, 32, 44, 94, 103, 123, 158, 233; analysis of compliance with, 126, 127; and benchmarking, 38, 96, 97, 98; case involving evaluation by, 8; and the credentialing process, 224; on disclosure, 109, 136, 139, 153; and evidentiary protection, 187–190; focus of, 34; initiatives of, 36–38; publication of, 28, 32*n*6, 37, 82, 108;

- and research reporting, 172, 174; root cause analysis model available from, 168; sentinel event policy of, 37, 121, 188; Six Sigma tools used by, 41; standards of, 2, 29, 175, 226, 230; and use of failure modes and effects analysis, 41, 45, 48–50, 52, 60. *See also* National Patient Safety Goals (NPSGs)
- Jordan, University of Texas Health Science Center v., 200, 218
- Judicial Conference of the United States, 211
- Jurors, expectations of, 138
- K**
- Kadzielski, M. A., 219, 223, 232, 234
- Kansas laws and regulations, 20, 32*n*2, 123*n*7, 18, 184, 186, 192, 194, 198, 203
- Kappas v. Chestnut Lodge, Inc., 201, 218
- Kennedy, D., 209
- Kennedy, E., 92
- Kentucky laws and regulations, 116, 123*n*7, 12, 193, 194, 198, 203
- Kimberlin v. U.S. Department of Justice, 211, 218
- Kinter, S. D., 104
- Kohn, L. T., 1, 15, 16, 17, 33, 34, 44, 91, 94, 117, 123, 232, 234
- Kraman, S. S., 153, 154, 158
- Kramer, Fox v., 201, 218
- Kutner v. Davenport, 200, 218
- L**
- Labels. *See* Drug labels; Medication labels
- Laboratories, patient safety standards for, setting, 187
- Lamb, J., 150, 158
- Larry, D., 225, 234
- Lasix, 65
- Late-entry notes, issue of, 109–110, 132
- Later Day Saints (LDS) Hospital, 76
- Latino, K. C., 46, 63
- Latino, R. J., 45, 46, 63
- Timothy Laubach et al v. Franklin Square Hospital, 110, 123
- Laudan, L., 142, 158
- “Launch of Shared Visions—New Pathways,” 38, 44
- Law enforcement officials, 112, 168
- Law firms, evaluating, benchmarks for, 130. *See also* Outside legal counsel
- Laws and regulations. *See* Federal laws and regulations; State laws and regulations
- Lawsuits, malpractice. *See* Malpractice lawsuits and litigation
- Lay practice, prohibiting, 222
- Leadership: future ideas for, 241; lack of, scenario depicting, 236; role of, in advancing patient safety, lessons on, 236–240
- Leadership education, need for, 241
- Leadership responsibilities, addressing, 4, 30–31, 39
- Leadership support, importance of, 20, 236
- LEAP™ Opportunity Analysis, 53–58, 59
- Leape, L., 21, 33, 64, 70, 75, 90, 93, 94
- Leapfrog Group, 35, 39, 40, 65, 98–99, 103, 227–228, 234
- Learning: from errors, importance of, 241; using benchmark data for, 100
- Leeway, providing, 12, 13
- Legal cases. *See specific cases*
- Legal counsel: forming guidelines for, 129–130, 131; involving, in developing standardized terminology, 14; referring concerns about adverse event reporting to, 173; retaining separate, 135; setting solid foundation for, 4. *See also* Outside legal counsel
- Legal files, managing, 133
- Legal protection. *See* Protection legislation
- Legal risk exposure, complex, dealing with, 134–136
- Lehman, B., 8–9, 70
- Leitch, A. G., 145, 157
- Lessons from the field, 236–240
- Leveraging peer review protections, 58, 60–62
- Levinson, W., 150, 158
- Liability: basis for, 10, 11; concerns over perceived admission of, 6, 23, 138, 153; corporate, 231; vulnerability to, risk of, analysis on, 52
- Liability exposure: determining, 125; possibility of, 177
- Liability insurance and tort reform, 17. *See also* Malpractice insurance crisis
- Licensed independent practitioner (LIP), 230
- Licensing board committees, 200
- Licensing boards: reporting to, 7, 9, 19, 125, 168, 233; working with, 225, 226, 227, 229
- Licensing frequency, 188
- Licensure agencies, 8, 19, 22, 187–188
- Life risks, 142, 146
- Life Safety Code, 40
- Life safety, norms for, setting, 35
- Life-threatening hazard, reporting requirement for, 120
- Limitation of clinical privileges, 222
- Litigation: costs of, avoiding, 70; from disclosure, 138–139; fear of, 91; involving device malfunction, 111; involving negligence, context for, 42; and late-entry notes, 109–110; maintaining confidentiality in the face of, protections for, 183–217; managing, responsibilities in, 107, 108, 110, 113–114, 116, 119. *See also* Malpractice lawsuits and litigation
- Livotte v. New York City Health and Hospitals Corporation, 116, 123
- Lloyd, A. J., 142, 144, 148, 158
- Localio, A. R., 89, 94
- Location, issue of, for disclosure conversations, 154
- Logic tree analysis, 52
- Lohr, K. N., 97, 103

- Long-term care facilities, patient safety standards for, setting, 36, 187
- Lorazepam, 83
- Losec, 65
- Loss, determining definition of, 54, 56
- Loss runs, managing, 133
- Louisiana laws and regulations, 188–189, 193, 198, 203
- Low-intensity ICU staffing, 228
- Lurie, P., 225, 234
- Lutheran General Hospital, Berger v., 196, 217
- M**
- Mad cow disease, risk of, 142
- Maine laws and regulations, 20, 32n2, 193, 198, 203
- Major event, meaning of, 49
- Malpractice claims, number of, and full disclosure, 154. *See also Claim entries*
- Malpractice counsel, retaining separate, 135. *See also* Outside legal counsel
- Malpractice history, obtaining, 225
- Malpractice insurance crisis, 16, 17, 19, 24, 89
- Malpractice lawsuits and litigation: basis for rulings in, 20; fear of, 18, 19, 183; incidence of, 89; reasons for most, 89–90, 152; settlements and awards rendered from, publicity surrounding, 104; use of terminology and data in, issue of, 3; using standards as evidence in, 17, 29; value of patient safety goals in, 28. *See also Claim entries; Litigation entries*
- Malpractice litigation analysis, 125, 126
- Managed Behavioral Healthcare Organization (MBHO) Accreditation Program, 38–39
- Managed care organizations, 229
- Mandatory reporting: federal, 26, 31, 118–120, 207, 208; overview of, 17–19; states with, 14n1, 20, 32n2, 117, 122–123n7, 184, 190; tips for understanding, 20–23. *See also specific reporting systems*
- Manufacturer and User Facility Device Experience (MAUDE) database, 207–208
- Manufacturers: reporting to, 25, 111, 120; warranty language of, 169–170
- Manufacturing, deviation in, defining, 208
- Marital communications privilege, 183, 210, 217
- Markakis, K. M., 89, 93
- Market share, shift in, possibility of provoking, 102
- Market withdrawal of drugs, 84–85
- Marketed medical products, problems associated with, reporting, 119–120, 208–209
- Martin, C., 232, 233, 234
- Marvel, M. K., 150, 158
- Maryland laws and regulations, 32n2, 115, 123n7, 18, 193, 194, 198, 201, 203
- Maryland Nursing Board, 229
- Massachusetts Board of Registration in Nursing, 9
- Massachusetts Department of Health, 8, 186
- Massachusetts, involvement of, with the Leapfrog Group, 99
- Massachusetts laws and regulations, 32n2, 123n7, 13, 153, 184, 186, 193, 194, 198, 203
- Massachusetts Nurses Association, 9, 15
- Massachusetts Organization of Nurse Executives, 9
- McConnell, J. C., 104
- McGlynn, E. A., 90, 98, 103
- McMaster v. Board of Psychology Examiners, 196, 218
- McMeekin, J., 67, 95
- Meadowlands Hospital Medical Center, Frank Reyes et al v., 121, 123
- Media relations, notifying, 112
- Medical boards, 7, 19, 168, 229. *See also* Licensing boards
- Medical Care Availability and Reduction of Error (MCare) Act, 14n1, 19, 20–23
- Medical device alerts, 111, 114
- Medical device, defining, 118
- Medical device reporting, 24–26, 109, 111, 114, 118–120, 172, 179, 207–208, 208–209
- Medical device reports (MDRs), protection of, 207–208
- Medical devices: demonstrated competencies in using, need for, 241; preserving, 113, 114, 169–170
- Medical directors, 238
- Medical error, defining, 30
- Medical error reporting. *See Reporting entries*
- Medical errors: barely averted, differing definitions for, 2; causes of, identifying, 209; concerns over reporting, 183–184; eliminating deaths and injuries from, sharing hope of, 12; goal for reducing, 1; as a leading cause of death, 1, 117; omissions and commissions in, delineating, suggestions about, 3; states referring to reporting of, 117. *See also specific type*
- Medical examiners, 112, 125, 168
- Medical Injury Compensation Reform Act (MICRA), 17
- Medical licenses, requests for, 224, 225. *See also* Licensing boards
- Medical records: copying and archiving, 132–133; documenting risk counseling discussion in, 149; electronic, 70, 90; exemption of, from disclosure, 190, 191, 192–194; federal protection of, 210–216; late-entry note in, 109–110, 132; physician-patient privilege applying to, issue of, 194–197; preserving, as evidence, 113; redacted copies of, disclosing, 195–196; requests for, and potential litigation, 108, 110; review of, 107, 109; separating incident reports from, 106, 115; sequestering of, 110, 132
- Medical records department, obtaining information from, 108, 132

- Medical residency programs, and work hour limitations, 2, 14*n*4
- Medical review committee, 201
- Medical schools, 141, 151, 225
- Medical slang, use of, problems caused by, example of, 150–151
- MedicAlert-style bracelets or necklaces, 165–166, 177–178
- Medicare and Medicaid: advent of, 104; billing of, analysis of, 127–128; conditions of participation in, 12, 16, 29–31, 35, 36, 173, 175; and decertification, 43; hospital termination from, 31
- Medicare services, review of, 214–215
- Medicare+Choice program guidelines, 213
- Medication administration record (MAR), 75, 76, 79
- Medication error, defining, 86
- Medication error reporting, 65, 67, 68, 71, 91–92, 121
- Medication errors: accountability for, and data sharing, concerns over, addressing, 8–9; analysis involving, 53; categorizing, system for, 67, 68; costs of, 93; human factors in, 85; identifying, for incident reporting, 105; insufficient training on, 89; potential for, turning into near misses, 237–238; states referring to reporting of, 117; top ten causes of, 77. *See also* Adverse drug events (ADEs)
- Medication labels, 81, 84. *See also* Drug labels
- Medication order process, failure in, 238
- Medication safety initiative model, 67–68, 69
- Medication storage area, 80
- Medication use process (MUP), 70, 71, 75–82
- Medications, reconciling, across the continuum of care, goal of, 229. *See also* Drug entries
- Medicine: doctrine of, 222; practice of, redefining, 235
- MEDMARX error reporting program, 67, 68, 71, 76, 77, 78, 83, 92, 121
- MEDSTAT recommendations, 209
- Medtronic, Community Hospital of Indianapolis v., 201, 217
- MedWatch, 119–120, 208–209
- Meeks, Suwannee County Hospital Corporation v., 200, 218
- Memorial Hospital, Sakosko v., 201, 218
- Mental errors, 85
- Mental health records, protection of, 213. *See also* Psychotherapist-patient privilege
- Meperidine, 83
- Merrell Dow Pharmaceuticals, Inc., Daubert v., 29, 32
- Methodist Hospital, Corrigan v., 200, 217
- Metoprolol, 83
- Michigan laws and regulations, 193, 198, 203
- Miller, A. R., 211, 218
- Milstein, A., 99, 103
- Minnesota laws and regulations, 14*n*5, 32*n*2, 40, 123*n*8, 13, 18, 193, 198, 203
- Minnesota Medical Board, 229
- Minor event, meaning of, 49
- Miscarriage, reporting requirement for, 120
- Mission and values statements, 130
- Mississippi laws and regulations, 123*n*17, 197, 199, 204
- Missouri laws and regulations, 193, 199, 200, 204
- Missouri Medical Board, 229
- Mistakes, awareness of being vulnerable to making, 240
- Moderate event, meaning of, 49
- Modification of clinical privileges, 222
- Monetary values, attaching: to adverse events, 107; to factual findings, 61, 76; to risk event projections, avoiding, 60
- Monitoring: of clinical response, 82; of e-mail traffic, 164, 168; of health professionals, 220–221; of high-risk trials, 178, 181; of medication, 70, 81–82; of multi-site trials, 178; of revised patient safety processes, 13
- Montana laws and regulations, 193, 199, 204
- Morbidity and mortality conferences, obtaining information from, 108
- Morphine, 83
- Mortality rates: expressing risk in terms of, 144; in intensive care units, 228; from medical error, 1. *See also* Deaths
- Moy, E., 225, 233
- Mulder v. VanKersen, 200, 218
- Multidisciplinary committees, 200
- Multidisciplinary sentinel event advisory group, 38
- Multiple fact finding layers, 134, 175
- Multiple law firms, 131, 135–136
- Multiple reporting obligations, 173, 174–175
- Multiple standards or processes, accommodation of, 13
- Multisite trials, 178, 181
- Murphy's Law, 64

N

- Narcotics, 83
- Narcotics Anonymous (NA) meetings, 221
- National Academy for State Health Policy, 18, 33, 184
- National Association Medical Staff Services, 223, 234
- National Center for Patient Safety, 49–50, 63
- National Committee for Quality Assurance (NCQA), 34, 38–39, 224
- National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), 67, 68, 81, 85–86, 94
- National Council on Patient Information and Education (NCPIE), 88, 89, 94
- National Fire Protection Association (NFPA), 35, 40, 44

- National Guideline Clearinghouse, 42, 43
- National Health Service, United Kingdom, 32n1
- National Institutes of Health (NIH), 26, 161, 179–180, 181, 182
- National Library of Medicine, 3
- National Nosocomial Infections Surveillance (NNIS) system, 206–207
- National Patient Safety Agency, 32n1
- National Patient Safety Foundation, 65
- National Patient Safety Goals (NPSGs), 16–17, 27–28, 32n5, 37–38, 228–229; and medication error reduction, 65, 66, 71, 76, 81, 85, 87, 88
- National Practitioner Data Bank, 226, 233
- National Quality Forum (NQF), 2, 14n5, 35, 39–40, 44, 96, 98
- National Quality Improvement Goals, 38
- Naylor, A. R., 142, 144, 148, 158
- Near miss, definition of, universal, need for, 14
- Near-miss data, protection of, issue of, 19
- Near-miss events: analysis of, 52, 53, 82; capturing, 67, 68; disclosure of, 136; versus good catches, 237–238; identifying, for incident reporting, 105, 106; terminology issues pertaining to, 2, 3
- Near-miss reporting, 19, 21, 24–26, 106
- Nebraska laws and regulations, 184, 193, 199, 204
- Nebraska Nursing Board, 229
- Need to know, valid, existence of, 211
- Negligence: context for, 11, 42; evidence of, concerns over, 6, 29, 67; finding of, facts needed for a, 125; forms of, 19; meaning of, 106; as rarely identified, 89. *See also* Malpractice lawsuits and litigation
- Neonatal care, high-risk, performance-based rules for, calls for, 96
- Nevada laws and regulations, 32n2, 193, 197, 199, 204
- Never events (as serious reportable events), 2, 14n5
- New Analysis Wizard, use of, 54, 55, 56
- New drug applications, investigational, requirements for, 26
- New Hampshire laws and regulations, 114, 193, 199, 204
- New Jersey laws and regulations, 18, 32n2, 121, 123n7, 184, 193, 199, 204
- New Mexico laws and regulations, 184, 193, 197, 199, 204
- New York City Health and Hospitals Corporation, Livotte v., 116, 123
- New York laws and regulations, 2, 14n1, 32n2, 123n7, 184, 186, 191, 193, 199, 204
- New York Patient Occurrence Reporting and Tracking System (NYPORTS), 14n1
- New York State Controlled Substance Act, 216
- New York State Department of Health, 101, 103, 186
- New Zealand, 35, 41
- Newly approved drugs, applying caution in using, 87–88
- Newman, Amente v., 195–196, 196–197, 217
- Nielson v. Bryson, 197, 218
- 9/11 event, 142
- Noncompliance: clear evidence of, 13; consequences of, 22, 31, 42–43, 52–53, 119, 220, 221, 222; reason for, 18; report addressing, 27
- North Carolina Board of Nursing, 229
- North Carolina laws and regulations, 123n7, 15, 184, 193, 199, 204
- North Carolina Medical Board, 229
- North Dakota laws and regulations, 193, 199, 204
- Nudell, T., xiv
- Nuremberg Code, 160
- Nurse managers, reporting to, 106
- Nurse-patient ratios, 2, 12, 14n3, 37
- Nurses: accountability of, and data sharing, concerns over, 8–9; and administering medication, 71, 75; assigning sicker patients to, 85; good catches by, 237; perspective of, 137; restricting access of, to medication, 64; standards for, legal concepts for, 10
- Nursing assistants, 85
- Nursing directors, 238
- Nursing Home Compare, 101
- Nursing licensing boards, 9, 229
- Nursing managers, 238
- Nursing shortage, 12
- O**
- O'Brien, 64
- Obstetrical and gynecological risks, comparing, to general life risks, 145–146
- Occasional occurrence, meaning of, 50
- Occurrences, law referring to, 20
- O'Connell, J., 19, 33
- O'Connor, A. M., 148, 158
- Office for Human Research Protections (OHRP), 161, 168, 178, 181
- Office for Protection from Research Risks (OPRR), 161
- Office of Inspector General (OIG), 161, 178, 179
- Office of Research Integrity, 173
- Ohio laws and regulations, 32n2, 123n7, 11, 16, 18, 184, 193, 199, 204
- Ohio Permanente Medical Group, Inc., Wall v., 200, 218
- Oklahoma laws and regulations, 193, 199, 205
- Olson, J. E., 145, 158
- Omissions, delineating commissions and, in medical errors, suggestions about, 3
- On-call personnel, providing instruction sheets to, 168
- On-call systems, 163–164, 177
- Ongoing communication, importance of, 175

- Ongoing counseling, 222
- Ongoing patient safety improvement, approach to, 13
- On-line reporting, 106, 120. *See also* Web-based reporting systems
- On-site accreditation surveys, 37, 188
- On-site compliance survey, 38
- On-site review process, 189, 190
- Open forums, use of, for involved personnel, 133–134
- Open ICUs, 227
- Openness, culture of, establishing, 79
- Opiates, 83
- Opportunity analysis, 52, 54, 56, 57, 60, 61
- Oral antidiabetics, 84
- Oregon laws and regulations, 184, 194, 197, 199, 205
- Oregon Medical Board, 229
- Oregon Nursing Board, 229
- Oregon Supreme Court, 197
- Organizational culture, 61, 79, 85, 87, 139; shift needed in, 100, 105, 232, 240
- Organizational laws, 61
- Osteopathic licensing boards, 229
- Outcome data, evidence-based, use of, for benchmarking, 97–98
- Outcome measures, 100
- Outcomes: categorizing medication errors by severity levels and, 67, 68; quantification of, 53–58; unanticipated, disclosure of, requiring, issue of, 136, 141, 175
- Outcomes improvement, 12
- Out-of-context reports, preempting use of, 3–4
- Outpatient medication error reduction, 71, 88–91
- Outside investigation, reasons for using, 116
- Outside legal counsel: coordinating defense strategies among, 135–136; employee representation by, recommending, 127; selecting and managing, 129–132; using team approach with, 125
- Outside standards, 99
- Overton, B., 195–196
- ## P
- Pacific Business Group on Health, 99
- Painting Industry of Hawaii v. Department of the Air Force, 213, 218
- Paling, J., 145–146, 158
- Paling Perspective Scale for Describing Risk, 145
- Paper-based prescriber ordering system, 75
- PA-PSRS Patient Safety Advisory, 23
- Pareto principle (80/20 rule), 50, 51, 56, 58
- Park, D. M., 152, 159
- Parkin, L. E., 183
- Parton v. U.S. Department of Justice, 211, 218
- Patient bills, abating, 112, 138
- Patient communication: free, encouraging, 139; issues impacting, 140; overseeing, 132; problems with, 89–90, 149–150; providing training on, 141; responsibility for, 112, 136, 137. *See also* Disclosure
- Patient concerns: communication of, interrupting, 149–150; resolving, 137–138, 139
- Patient controlled analgesia (PCA), 83, 85, 87
- Patient decision making, 146–148
- Patient disclosure. *See* Disclosure
- Patient experience of care information, 38
- Patient falls, 229, 237
- Patient identification, improving, 27, 66, 81
- Patient information, lack of, addressing, 90
- Patient names, similar, problem of, 78
- Patient record documentation, 137. *See also* Medical records
- Patient reminders, 164–165, 168
- Patient safety: as a buzzword or slogan, preventing eventual use of, importance of, 235; constraints on, legal and regulatory influences as, 5–9; as an evolving concept, 2; increased concern over, 1–2; terms defining, 2–5
- Patient Safety: Achieving a New Standard for Care* (Institute of Medicine), 2, 3
- Patient Safety and Quality Improvement Act, 24, 65, 91–93
- Patient safety committees: designating, and assigning responsibilities, 21–22; protections for, 23
- Patient Safety Data System, 209
- Patient safety goals, recommended. *See* National Patient Safety Goals (NPSGs)
- Patient Safety Improvement Act, 23, 210, 215
- Patient safety indicators, promotion of, 2, 14n5
- Patient safety movement, 7, 17, 18, 26
- Patient safety officers, designating, and assigning responsibilities, 21
- Patient safety organizations (PSOs), 23, 65, 67, 92
- Patient safety plan, 21, 22
- Patient safety programs, 16, 20, 21
- Patient safety rounds, 238–239
- Patient safety standards: achieving and maintaining, practical approach to, 13–14; calls for, by payors, example of, 99; for continuum of care, design of, 2; establishing, consequences of, consideration of, 12; legal and regulatory consequences of, 28–29, 42–43; legal significance of, 11–13; putting into effect, 36; sources for, 34–35, 175; strategies for setting, 43. *See also* National Patient Safety Goals (NPSGs); Standards of care
- Patient Safety Task Force, 209
- Patient safety trust fund, 21
- Patient treatment, attending to, following an adverse event, 106, 167
- Patient-institutional relationship, maintaining, 153
- Patients: educational level of, and understanding informed consent forms, 148–149; as partners in treatment, 235; perception of, about risk, 142; recall ability of, issues with, 145, 148; working to better inform, 241

- Payne v. Howard, 194–195, 218
- Payors, use of benchmark data by, 98–99
- Pediatric preventive measures, 230
- Peer review committees, 186, 236
- Peer review organization (PRO), 214–215, 227
- Peer review process, involving others in, 7
- Peer review protections, 18, 19, 24, 114, 116, 133, 197, 200–201; analysis of, 201, 202–206; leveraging, 58, 60–62
- Pendrak, R. F., 83, 84, 93
- Pennsylvania Health Department, 19, 22, 187, 188
- Pennsylvania laws and regulations, 2, 14*n*1, 18, 19, 20–23, 32*n*2, 123*n*7, 15, 17, 184, 185, 187, 188, 194, 199, 205
- Pennsylvania Patient Safety Authority, 19, 21, 22, 32*n*3, 33
- Pennsylvania Patient Safety Reporting System (PA-PSRS), 23
- Percentage of risk, interpretation of, by patients, 143–144
- Performance feedback, use of, 97, 98
- Performance improvement activities and projects, requirements for, 30
- Performance improvement, as prerequisite, 102
- Performance improvement process, accountable for having, 233
- Performance-based rules, calls for, 99
- Periodic performance report (PPR) options, 38
- Personal clues about patients, 150
- Personalizing risk, problem with, 145
- Pharmacies: and computerized prescriber ordered entry, 76; restricting items to, 64; signage at, 164, 165
- Pharmacists: accountability of, and data sharing, concerns over, 8, 9; clarification by, versus guessing, 90; clinical, increasing use of, 70; good catches by, 237; medication order review by, 80; safety check by, 85
- Pharmacotherapy, quality of, improving, impairing efforts at, 91–92
- Pharmacy directors, 238
- Pharmacy meetings, obtaining information from, 108
- PHILCO Insurance Company, 83–84
- Phone rollover service, providing, 177
- Physician care measures, 230
- Physician, definition of, 194
- Physician Group Quality Profile Report, 229–230
- Physician health programs, 226, 231
- Physician report cards, 229–230
- Physician-patient privilege, 183, 191, 194–197, 198–199, 210, 216
- Physicians: perspective of, 137; providing feedback to, 85; recovering from disabilities, providing assistance to, 227; in training, standards for supervising, 230–231; views of, adjustment in, need for, 89
- Policy statements, 130
- Polypharmacotherapy, 89
- Popp, P. L., 124
- Posicor, 85
- Position statements, 42
- Potassium chloride, concentrated (KCl), 64–65
- Potential events, capture of, 67, 68
- Potential injury, states referring to, 117
- Practical tools and training, providing, 241
- Practitioner Remediation and Enhancement Partnership (PREP), 229, 230
- Precursors, 19. *See also* Near-miss events
- Premature disclosure, pressure to make, 180
- Preprinted order forms, use of, 86
- Prescribing medication, 70, 71, 75–78, 79, 86–87
- Prescriptions filled, retail, number of, 88
- Prescriber training, 86–87
- Prescribing practices, information about, 88
- Prescription writing, 70, 87, 90
- “Prescription Writing: A Mini Learning Module,” 86
- Preserving evidence, strategies for, 110, 111, 113–114, 169–170
- Preventable adverse drug events: percentage of claims deemed as, 183; reduction in, 70, 76
- Preventable event, meaning of, importance of, 86
- Preventing future errors, database for, 23
- Preventing reoccurrences, 127, 128, 135
- Prevention, responsibility for, and health care system design, 64
- Preventive actions: determining needed, 127; reporting, 121
- Preventive care measures, 230
- Prilosec, 65
- Primary and secondary event types, employing, suggestion of, 3
- Primary insurance carriers, notifying, 112
- Priority focus process (PFP), 38
- Priority identification, 52, 60
- Priority setting, 13
- Privacy Act, 211
- Privacy concerns, balancing, with disclosure interests, 191, 192–194, 195–196, 212, 216, 217
- Private insurance funding, introduction of, 104
- Privileged communications and information, protection of. *See* Confidentiality; Protection legislation
- Privileged designation. *See specific privilege*
- PROACT software, 168
- Proactive adverse-event management, 108–117
- Proactive risk identification, 107–108
- Probabilistic data, use of, 54
- Probability rating, 47, 49–50
- Process flowchart, 56, 57
- Process identification, 170–171
- Process improvement, identifying, 171
- Process indicators, use of, 170–171

- Process of care measures, 97–98, 100
- Process questions, 171
- Product labels, 209
- Professional bylaws, rules and regulations, disciplinary actions contained in, 7–8, 222–223
- Professional compliance, managing, aspects of, 219–233
- Professional counseling, receiving, 221, 222
- Professional disclosure standards, 152–153
- Professional education, 227, 229
- Professional liability claims
- Professional liability claims, basis for, 10, 11
- Programmable infusion devices, 81
- Projected risks, focusing on, 60
- Prompts (process indicators), use of, 170–171
- Pronovost, P.J., 96, 98, 99, 103, 228
- Property rights, professional, 223
- Proportion of risk, patient understanding of, 144
- Propulsid, 85
- Prospective employees and staff, prerequisites for, 231
- Protected health information (PHI), use of, under HIPAA, 214
- Protection legislation: determining coverage under, 23, 110, 114, 115; for disclosure conversation, 14*n*2, 153; federal, 23–24, 65, 91–92; involving privilege, 191, 194; in medical device reporting, 25–26; need for, 6, 18, 67, 122; proposed, 122; regarding discovery, 184–185; and self-critical analysis, 121; states with, 114, 122*n*1–6. *See also* Confidentiality; Evidentiary protection
- Protective orders, 211
- Providers. *See specific type*
- Provisional accreditation, 27
- Psychotherapist-patient privilege, 191, 196, 198–199, 210, 216–217
- Public opinion, misguided, 104
- Public records: access to, 190, 200; definition of, exclusion of medical records from, 191, 192–194
- Publicity: and human research, 160; negative, fear of, 18; surrounding large settlements and awards, effect of, 104
- Punitive approach, issues concerning, 7, 8, 9. *See also* Blame
- Purchasing specifications, creation of, 98–99
- Purpose of reports, awareness of, 174

Q

- Quality: achieving and maintaining, providing latitude for, 12, 13; as an operative phrase, 35; promotion of, accrediting organizations sharing idea of, 34
- Quality assessment and performance improvement (QAPI) regulation, 12–13, 29–31, 39, 41, 101
- Quality assurance committees: dilemma for, 236; protection of, 114–115, 119, 133, 201
- Quality assurance, continuous, in human research, 167
- Quality assurance directors, 238
- Quality focus, 219
- Quality improvement: continuous, approach to, 35; costs of, versus medication errors, 93; new advances in, case for using, 68; process of, involving others in, 7
- Quality improvement meetings, 87
- Quality improvement programs: development and implementation of, 29–31; requiring, 187
- Quality indicator data, use of, requiring, 30
- Quality Interagency Coordination Task Force (QuIC), 1, 15, 30, 33
- Quality management department, 106, 107, 108, 114
- Quality management perspective, 53
- Quality measures, 96, 97, 98, 99–100, 102. *See also* Standards of care
- Quality of care, defined, 97
- Quality of care problems, states referring to reporting of, 117
- Quality reports, 38
- Quality review committees and programs, 114, 116

- Quality reviews, obtaining information from, 108
- Quality-of-care evaluation committees, 200
- Quantification: of outcomes, 53–58; of risk, 143, 144

R

- RAND Corporation, 90
- Random survey, 27
- Rank prioritization number (RPN), 53
- Rare adverse drug reactions, 87–88
- Rate of risk, patient understanding of, 144
- Ray, U.S. Department of State v., 212, 218
- Read back of orders, 91. *See also* Repeat-back technique
- Reardon, T. R., 18, 33
- Recall ability, 145, 148
- Redacted copies, 195–196, 207, 212. *See also* Deidentified information
- Redmond, Jaffee v., 216–217, 218
- Redundancy, certain amount of, importance of, 167
- Regional rollouts, 99
- Regular-acting formula, 90
- Reimbursement rates, 13
- Relationships, provider-patient, change in, encompassing, 235
- Relative risk, distinguishing absolute risk from, 143
- Reliability Center, 53, 54, 55, 57, 58, 59, 63, 168
- Reliability of measures, 102
- Reminders, providing, for patients to reveal participation in clinical trials, 164–165, 168
- Remote occurrence, meaning of, 50
- Renal failure, acute, 88
- Reoccurrences, preventing, 127, 128, 135
- Repeat-back techniques, 91, 149, 156
- Report cards, physician, 229–230
- Report data, uses of, 105
- Report writing, 106
- Reportable data, 22
- Reportable events: identifying, for data capture, 105–106; separate categories of, determining, 22;

- states specifying type of, 117, 186; variance in defining, 20–21, 117. *See also specific type*
- Reportable incidents, states referring to, 20, 186
- Reporting: deterrent to, identifying adverse events as, issue of, 6; encouraging, laws designed for, 2, 14*n*2, 65, 91; framework for, enhancing, 9; initial step in, 109. *See also specific type*
- Reporting failure, consequences of, 22
- Reporting forms, specific, use of, 25, 120
- Reporting, laws protecting. *See* Protection legislation
- Reporting matrix, developing, 173
- Reporting policies or guidelines, having, in place, 109
- Reports, incident. *See* Incident reports
- Reproduction of documentation, 169. *See also* Copies
- Reproductive Services v. Walker, 211, 218
- Requirement of improvement, receiving, 27
- Research and analysis efforts, coordinating, 209
- Research bracelets or necklaces, 165–166
- Research consent documents, 177
- Research environment, safe, creating, 162–167
- Research privacy, 213–214
- Research protocols: constructing, assistance in, 178–182; ensuring, tools for, 167; name of, providing, 166, 178; road map for creating and implementing, providing, 160
- Research-related adverse events: participants reporting, 163, 176; reporting, 26–27, 172–175; responding to, 167–178
- Reserves, placing, on incidents, 107
- Residency education programs, and work hour limitations, 2, 14*n*4
- Residency Review Committee Program of the Accreditation Council for Graduate Medical Education, 14*n*4
- Residency training facility, becoming designated as, 36
- Resident supervision, 230–231
- Residual surveys, 188
- Resolution procedures, outlining, 129
- Responsibility, need for, 90
- Retail pharmacy signage, 164, 165
- Retail prescriptions filled, number of, 88
- Retained instruments or sponge, possibility of, 144
- Retraining needs, assessing, 128
- Reviewable events, determining what constitutes, 172
- Revocation, 8, 222
- Frank Reyes et al v. Meadowlands Hospital Medical Center, 121, 123
- Rhode Island Department of Health and Human Services, 117
- Rhode Island laws and regulations, 32*n*2, 117, 123*n*7, 17, 184, 194, 199, 205
- Rhode Island Medical Board, 229
- Riley, T., 2, 14, 18, 33, 184, 218
- Ripple effect, addressing, 124–128
- Risk: art of describing, 141–145; defining, 143; patient decision making about, example of, 146–147; perceived, issue of, 142; perceptions of, differences in, 149
- Risk activities, individuals engaging in, 142, 143
- Risk adjustment, 144
- Risk analysis, 125–128
- Risk areas, identifying, 104, 105, 107–108, 239
- Risk assessment index, 3
- Risk assessment, new advances in, case for using, 68
- Risk counseling, offering, concepts for use in, 148–149
- Risk exposure, legal, dealing with, 134–136
- Risk management: framework for, standards setting, 41; as an operative phrase, 35; perspective of, 53
- Risk management audit, conducting, 87
- Risk management department: dealing with claims management risks, 124–139; failure to report directly to, consequences of, 116; forwarding requests for medical records to, 108, 110; interviews conducted by, 110–111; involving, in developing standardized terminology, 14; and preserving evidence, 114; referring reporting concerns to, 173; reporting to, 106, 107, 109, 119
- Risk Management PEARLS for Medication Error Reduction* (Benjamin), 85
- Risk management proceedings, protection of, 114, 115, 119
- Risk management tools, 68
- Risk numbers, significance of, to patients, 143–144, 148
- Risk prevalence, tool for describing, 145
- Risk profiling, 144, 145–146
- Risk-adjusted benchmark data, 100
- Risks, projected, focusing on, 60
- Roberts v. Department of Health and Human Services, 212, 218
- Robinson, A. R., 183, 218
- Robinson, F., 183
- Roe, Whalen v., 216, 218
- Rollouts, regional, 99
- Room arrangement, consideration of, for disclosure conversations, 155
- Roosevelt Hospital, Williams v., 191, 218
- Root cause analysis (RCA): conducting, 37, 41, 53, 57, 58, 67, 87, 127; confidentiality of, 189, 190; connotation of, 52; focus of, 125; managing data from, 133; models for, 168; reporting results of, 121, 174; requiring, 188; writing up reports for, 60, 61
- Root cause failure analysis (RCFA), connotations of, consideration of, 51, 52
- Rosebraugh, C. J., 89, 95
- Rosenthal, J., 18, 33, 184, 218
- Rosner, F., 152, 158
- Rothschild, J. M., 183, 218

- Routine use, defined, 211
 Routine use exception, 211
 Royston, G.H.D., 143, 157
 Rozovsky, F. A., 1, 34, 60, 63, 96, 141, 155, 158, 159, 235
 Rubin, H. R., 97, 103
 Run charts, 41, 100
 Running log of issues, maintaining, 238
- S**
- Safe harbor rule, 214
 Safe Medical Devices Act (SMDA), 24–25, 26, 111, 118–119, 172
 Safe practices, categories of, 39–40
Safe Practices for Better Healthcare: A Consensus Report (National Quality Forum), 39
 Safer environment, creating, for clinical trials, 162–167
 Safety check, 76, 85
 Safety courses, stagnant, problem of, 48–49
 Safety models, availability of, 68
 Safety nets, 85, 156, 165
 Safety technology, availability of, 68
 St. Paul Fire and Marine Insurance Co., Cochran v., 195, 196–197, 217
 Sakosko v. Memorial Hospital, 201, 218
 Salary freeze, 222
 Sanctions, 8, 9, 225
 Santa Rosa Memorial Hospital v. Superior Court, 200, 201, 218
 Santell, J. P., 64, 67, 95
 Scheduled surveys, 27, 190
 Schenk, D. R., 150, 157
 Schroeder, S. A., 97, 103
 Scientific community, representation from, on data and safety monitoring boards, 180
 Scope of analysis, 52–53, 54
 Screening tools, employing, for research participants, 162
 Seldane, 85
 Self-critical analysis, protection of, issue of, 121–122
 Self-insured institutions, 107
 Sentinel event advisory group, 38
Sentinel Event Alerts, 28, 32n6, 37, 82, 108
 Sentinel event, definition of, 82, 108, 121, 188
 Sentinel event policy, 37, 121, 188
 Sentinel event reviews, obtaining information from, 108
 Sentinel events: analysis involving, 52, 53; confidentiality of reporting, 189–190; law referring to, 20–21; qualifying as, 127
 September 11, 2001 event, 142
 Sequestration, 110, 111, 113, 114, 169–170
 Serious adverse events, identifying, for incident reporting, 106
 Serious events, state referring to reporting of, 21, 187
 Serious illness, definition of, 118
 Serious incidents and accidents, states referring to, 186
 Serious injury data, protection of, issue of, 19
 Serious injury, definition of, 25, 118
 Serious reportable events (as never events), 2, 14n5
 Severity of impact rating, 56
 Severity of injury: as determining factor for reporting action, 106; focusing analysis on, methods for, 56
 Severity ratings: assigning, 46, 47, 56, 107; categorizing medication errors by, 67, 68; classifications of, 49, 50
 Shader, R. I., 86, 95
 Shared Visions—New Pathways approach, 38
 Sharing privileged information with third parties, legal concerns over. *See* Confidentiality; Evidentiary protection
 Shredding copies, 189
 Sick cell anemia patients, 214
 Side effects, reporting, 162–163, 209
 Signage, importance of, 164–165
 Significant few events: calculation of, 57; charting, 50, 51, 58, 59; identifying, 56, 58
 Significant proctoring of clinical privileges, 222
 Significant risk, determining what constitutes, 143–144
 Similar drug names, 65, 71, 77, 90, 91
 Similar patient names, 78
 Simplification, 71, 75, 78, 148
 Singh, A. D., 145, 158
 Six Sigma methods, incorporating, 35, 41
 Slang, medical, use of, problems caused by, example of, 150–151
 Sloan, F. A., 152, 158
 Small facilities, medication error prevention for, 86–88
 Smallpox vaccine adverse-event reporting, 31
 “Smallpox Vaccine Adverse Events Monitoring and Response System for the First State of the Smallpox Vaccination Program,” 31, 33
 Smart pumps, 81
 Smith, A. F., 142, 157
 Snively, G. R., 144, 158
 Social Security Act, 213, 215
 Solomon, R. P., 16
 South Carolina Department of Health Licensing, 187
 South Carolina laws and regulations, 32n2, 123n7,9,17, 184, 187, 194, 199, 205
 South Carolina Nursing Board, 229
 South Dakota laws and regulations, 32n2, 123n7,9,17, 184, 194, 197, 199, 205
 Specialist, concept of, expectation surrounding, 10, 11
 Specialty board certification, 224, 225
 Speculation, avoiding, importance of, 106, 113, 137
 Spokespersons, selecting, 112
 Spoliation claims, 110
 Sponsors: obligation to report to, 172, 174, 176, 181; reporting by, requirements for, 174, 181; responsibility of, for data monitoring, 178, 179, 180
 Spousal privilege. *See* Marital communications privilege
 Staff appointment, 224–225, 231

- Staff committee proceedings, protection of, 114, 200, 201
- Staff educational program, counsel holding, 135
- Staff familiarity, with policies and procedures, 81
- Staff membership, professional, governing documents of, 222
- Staff reappointment, 225, 231
- Staff supervision, issue of, 230–231
- Staff training and education.
See Training
- Staffed call centers, providing, 177
- Staffing analysis, 126, 128
- Staffing intensive care units, 227
- Staffing ratios, 37, 223
- Staffing shortages, 12, 13
- Stagnant safety courses, problem of, 48–49
- Stalhandske, E., xiv
- Stallings, S. P., 145–146, 158
- Standard adaptation, 43
- Standard, universal definition of, need for, 14
- Standardization: in defenses, establishing, 130; incorporating, for medication safety, 67, 71, 72–75, 78, 81, 82, 86; need for, 2–4, 14; in reporting system, use of, 207
- Standards Australia, 41
- Standards for Health Care Facilities* (National Fire Protection Association), 40
- Standards New Zealand, 41
- Standards of care: attention to, 42; benchmark data for use as, 99–101; legal concepts of, 9–11
- Standards of patient safety.
See Patient safety standards
- Standard-setting organizations.
See specific organizations
- “Start low—go slow” adage, 88
- State compliance analysis, 125, 126, 127
- State ex rel. St. John’s Mercy Medical Center v. Hoester, 200, 218
- State freedom of information acts, 190–191, 192–194
- State health departments: and benchmarking, 101, 103; public access to, issue of, 190; reporting to, states requiring, 118, 123n17, 185, 186, 187; responsibility of, 21
- State laws and regulations: changes in, and reporting matrices, 173; on confidentiality protection, 6, 18; on disclosure conversations, 153; versus federal rules, 20; on freedom of information, 190–191, 192–194; on the horizon, 122; increase in, 16; providing evidentiary protection, 184–185, 186, 187; on reporting, 1–2, 14n1, 20, 117–118, 122–123n7–18, 184, 185–187. *See also individual states and regulatory agencies*
- State licensing agencies and boards.
See Licensing boards; Licensure agencies
- Statistical process controls (SPCs), 11, 41, 100
- Stein, G., 11
- Stephens, Doe v., 211, 217
- Stevens-Johnson syndrome, 87
- Stewart, J. B., 230, 234
- Stillbirth, reporting requirement for, 120
- Stress, 85, 221
- Studdert, D., 17, 33
- Subsequent public disclosure, protection from. *See* Evidentiary protection
- Subspecialty certificates, 227–228
- Substance abuse records, protection of, 213
- Subsystem failure, potential, analysis of. *See* Failure modes and effects analysis (FMEA)
- Suchman, A. L., 89, 93
- Summary actions, 222
- Summary reports, 119, 181, 185, 186
- Superior Court, John C. Lincoln Hospital and Health Center v., 201, 218
- Superior Court, Santa Rosa Memorial Hospital v., 200, 201, 218
- Support staff communications, 132
- Support systems, 61–62, 134
- Surgeries, wrong, eliminating, 28, 66
- Surgical procedures, performance-based rules for, calls for, 99
- Survival rate, expressing risk in terms of, 144
- Suspension, 8, 220, 221, 222
- Sustained-release (SR) formulation, 90
- Suwannee County Hospital Corporation v. Meeks, 200, 218
- Swango, M., 230
- Switzerland, 40
- Sympathy, expression of, and liability concerns, 14n2, 153
- System failure, potential, analysis of.
See Failure modes and effects analysis (FMEA)
- System failures, determining, following adverse events, 127, 168
- System simplification, 71
- Systemic change, calls for, 1–2
- Systemic failures: awareness of, 7, 9; early warning of, 237
- Systemized Nomenclature of Human and Veterinary Medicine (SNOMED CT), 3
- Systems failure and human failure, 169
- Systems focus approach, 125, 154.
See also Root cause analysis (RCA)
- Systems innovation, providing opportunity for, 240
- Systems redesign, taking action toward, 65

T

- Tax Analysts, U.S. Department of Justice v., 212, 218
- Team approach: to preventing errors, moving towards, importance of, 232; using, with outside legal counsel, 125
- Team building, importance of, 239–240
- Team effort, 85, 239–240
- Team members: communication between, 240; fostering familiarity among, 239; procedures for notifying, having, 167
- Technological advances, support systems keeping up with, issue of, 61–62

- Telephone numbers, providing toll-free, 166, 177
- Telephone prescription orders, problem with, 91
- Temple, Ekstrom v., 201, 218
- Temporary suspension, 220, 221, 222
- Tenhave, T. R., 149, 158
- Tennessee Department of Human Services, 187
- Tennessee laws and regulations, 32*n*2, 123*n*7, 184, 187, 194, 199, 205
- Termination: of employees, 10, 128, 220, 222; of hospitals, from Medicare and Medicaid, 31
- Terminology: connotations of, consideration of, 51–52, 53; and peer review protections, 60; standardized, need for development of, 2, 3–4, 14; using less offensive, 52, 53, 60; variance in, surrounding reportable events, 20–21, 117
- Terrorist attack, risk of, 142
- Testimony protection, 196, 200–201
- Texas Department of Health, 188
Texas Health & Safety Code, 188
- Texas laws and regulations, 32*n*2, 153, 184, 188, 194, 197, 199, 205
- Therapeutic nihilists, 88
- Third parties, sharing information with, legal concerns over. *See* Confidentiality; Evidentiary protection
- Third-party patient records, protection of, issue of, 195–196
- 360-degree analysis, 13
- 3M, 99
- Time: allowing adequate, for disclosure conversation, 154; standards changing over, the law anticipating, 11
- Timely reporting, requiring, 14*n*1, 107, 109, 117, 118, 186, 187, 208
- Timely response for message systems, importance of, 164, 177
- Time-out process, 239
- To Err is Human: Building a Safer Health System* (Kohn, Corrigan, and Donaldson), 1, 16, 34, 91, 136, 161, 232
- Toll-free numbers, providing, 166, 177
- Tort reform, 16, 17, 19
- Tort system, versus patient safety movement, 17, 18
- Toxic epidermal necrolysis (TEN), 87–88
- Tracking of devices, requiring, 118
- Trade secrets, deleting, 207
- Training: on the importance of reporting, 173–174; on incident reporting, 106; and medication error reduction, 85, 86–87, 89; need for, on interpretation of evidence-based data, 102; practical, providing, 241; for preventing reoccurrences, 128; in provider-patient communication, 141; on reporting requirements, 20; on safety practices for clinical trials, 166
- Training facility, residency, being designated as, 36
- Tranquilizers, 83
- Transcription, 70, 75, 79, 91
- Treatment choices, patient participation in, 148, 150
- Trends, identifying, 23, 54
- Trust: developing, between staff and risk management, 110–111; lack of, in reporting systems, 18; in outside counsel, building, 132
- Truth-telling in medicine, meaning of, issues with, 151–152
- Tufts Health Plan, 229, 230, 234
- Tufts University School of Medicine, 86
- Tully, D. A., 149, 158
- Turf battles, 137
- U**
- Umbrella protective orders, 211
- Unaffected research participants, disclosing adverse events to, issue of, 176
- Unanticipated outcomes, disclosure of, requiring, issue of, 136, 141, 175
- Uncommon occurrence, meaning of, 50
- Underreporting, 18, 67, 105
- Unionized health care environment, 223
- Unit supervisor, reporting to, 106
- Unit-dose form, dispensing in, 80
- United Kingdom, 32*n*1, 35
- U.S. Department of Health and Human Services (HHS), 23, 26, 161, 174, 178, 179, 181, 182, 209, 212, 218
- U.S. Department of Justice, Kimberlin v., 211, 218
- U.S. Department of Justice, Parton v., 211, 218
- U.S. Department of Justice v. Tax Analysts, 212, 218
- U.S. Department of State v. Ray, 212, 218
- U.S. Food and Drug Administration (FDA), 24–25, 65, 81, 85, 94, 111, 118, 119–120, 182, 207–209, 215; and human research, 26, 168, 174, 178, 179, 180, 181
- United States Pharmacopeia (USP), 65, 67–68, 69, 71, 75, 76, 77–78, 78–82, 83, 85, 92, 95
- U.S. Supreme Court, 29, 211, 212, 216, 217
- United States v. AT&T, 183, 218
- Unit-of-use package, dispensing, 81
- University of Colorado Health Sciences Center, 183
- University of Rochester, 238
- University of Rochester Strong Memorial Hospital, 153, 158
- University of Texas Health Science Center v. Jordan, 200, 218
- Unusual occurrence, states referring to, 117
- URAC, 224
- User facility, broad definition of, 25
- Utah laws and regulations, 32*n*2, 123*n*7, 17, 199, 205
- V**
- Vaccinations, 31
- Vaccinia Immune Globulin (VIG), 31
- Validation survey, process of, 36

- Validity of measures, 102
 Values and mission statements, 130
 Vancomycin, 83
 VanKersen, Mulder v., 200, 218
 Verbal information, patient
 difficulty recalling, 145, 148
 Verified copies, importance of, 169
 Verizon, 99
 Vermont laws and regulations, 190,
 194, 199, 205
 Veterans Administration (VA), 49,
 50, 63, 81, 154, 211
 Veterans Health Administration, 214
 Virginia Department of Health
 Professions, 101, 103, 205
 Virginia laws and regulations,
 194, 199
 Visual algorithms, use of, 171
 Volume-based rules, calls for, 99
 Voluntary reporting: federal, 23, 24,
 119–120, 206–207, 208–209;
 internal, encouraging, 121–122,
 184, 187–188; state, 1–2, 14n1,
 117, 123n8, 184. *See also specific
 reporting systems*
 Voluntary standards, significance of
 setting, 42
 Vulnerability, human, awareness
 of, 240
- W**
- Waived consent, 179
 Waived privilege, 113, 183, 188, 197
 Walker, Reproductive Services v.,
 211, 218
 Wall v. Ohio Permanente Medical
 Group, Inc., 200, 218
- Ward personnel, drawing input
 from, 239
 Warfarin, 83
 Warning bracelets or necklaces,
 165–166, 177–178
 Warning labels, 238
 Warning systems, early, 18
 Washington Health Depart-
 ment, 187
 Washington laws and regulations,
 32n2, 123n7, 18, 184, 185, 187,
 194, 199, 205
Washington Post, 90
 Web sites: interactive, for research
 participant use, 164; posting
 clinical trial information on, for
 provider use, 166
 Web-based reporting system,
 14n1, 23, 67, 121. *See also*
 On-line reporting
 Web-based teaching program, 86
 Weighted benchmark data, 100
 Weights and measures, expressing,
 using standard abbreviations
 for, 79
 West Virginia Board of Examiners
 for Licensed Practical Nurses, 229
 West Virginia laws and regulations,
 194, 199, 206
 Whalen v. Roe, 216, 218
 Whelan, T., 148, 159
 Whistle-blower situations, dealing
 with, 133–134
 Wigmore, J. H., 210, 218
 Williams, R. L., 65, 71, 79, 80, 81,
 82, 83, 94
 Williams v. Roosevelt Hospital,
 191, 218
- Wisconsin laws and regulations,
 194, 199, 206
 Witch-hunting philosophy, 61.
 See also Blame
 Witman, A. B., 152, 159
 Wolfe, S. M., 225, 234
 Woods, J. R., Jr., 140, 141, 142,
 155, 159, 235
 World Health Organization
 (WHO), 3, 32n1, 33
 Wright, C. A., 211, 218
 Written evidence, preserving
 information as, 113
 Written information, patient ability
 to recall, 145, 148
 Written notification, requiring, 19, 22
 Wrong-dose errors, 77, 78, 84,
 90–91
 Wrong-drug errors, 77, 78, 84
 Wrong-patient errors, 28, 66, 78,
 81, 84
 Wrong-procedure errors, 28, 66
 Wrong-route errors, 84
 Wrong-site errors, 28, 66
 Wrong-time errors, 84
 Wu, A. W., 154, 159
 Wyoming laws and regulations, 184,
 199, 206
- X**
- X-ray films, 109, 113
- Y**
- York v. American Medical Systems,
 207–208, 218
 Yutan, E., 150, 157

