Top Management & Performance Challenges Facing HHS





Department of Health and Human Services
Office of Inspector General

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Introduction

Every year, the Department of Health and Human Services (HHS or the Department), Office of Inspector General (OIG) fulfills its statutory obligation to produce the *Top Management and Performance Challenges Facing HHS*. While the Department has made efforts to address the challenges that we identify in this document, considerable opportunities exist for further progress. This document helps the Department fulfill its mission to enhance the health and well-being of all Americans by directing the Department's focus on the top management and performance challenges identified by OIG.

OIG's <u>website</u> offers additional oversight resources, including all reports mentioned here, OIG <u>recommendations</u> to improve Department programs and reduce vulnerabilities, and the status of those recommendations.



1 | Safeguarding Public Health

Elements of the Challenge

- Addressing the mental health and substance use disorder crises
- Improving maternal health
- Strengthening emergency preparedness and response capabilities
- Ensuring the safety, effectiveness, and availability of Food and Drug Administration-regulated products

HHS must work to better safeguard public health, including the following key areas:

Addressing the Mental Health and Substance Use Disorder Crises

In 2021, more than 1 in 5 American adolescents had a major depressive episode, nearly 1 in 4 American adults experienced mental illness, nearly 1 in 6 Americans had a substance use disorder, more than 48,000 Americans died by suicide, and more than 100,000 Americans died from drug overdoses. Challenges obtaining high-quality care for mental health and substance use compound the devasting effects of the Nation's mental health and substance use disorder crises.

HHS programs must improve behavioral health care and supports, such as by expanding community-based prevention efforts, enhancing access to affordable behavioral health treatments, and developing a diverse behavioral health workforce that can serve the public well and meet the needs of people from diverse backgrounds, understandings, and communication abilities.

2021 Behavioral Health Snapshot 1 in 5 adolescents had a major depressive episode 1 in 4 adults experienced mental illness 1 in 6 people had a substance use disorder 100,000+ people died of drug overdose 48,000+ people died by suicide = 1,000 Americans Source: Substance Abuse and Mental Health Services Administration

Improving Maternal Health

Too many Americans die during pregnancy, childbirth, and the postpartum period. More than 4 in 5 of these pregnancy-related deaths are preventable. Black people, American Indian and Alaska Native people, and residents of rural areas suffer disproportionately high rates of maternal mortality and other pregnancy complications. The Department must work to improve pregnancy-related care and eliminate racial, ethnic, geographic, and socioeconomic disparities in health outcomes for parents and newborns.

Strengthening Emergency Preparedness and Response Capabilities

Public health emergencies (PHEs), such as communicable diseases and storms, fires, and human-caused disasters, severely strain public health and medical infrastructure.

As PHEs increase in frequency and severity, HHS must build resilience and enhance preparation and response efforts to limit negative impacts on HHS programs and the public when these emergencies occur. Additionally, HHS must strengthen the Nation's emergency preparedness and response capabilities by enhancing public health infrastructure, including establishing highly functional data systems with accurate information about risk and response, a well-developed public health workforce, and mechanisms for effective coordination with States, localities, Tribes, and Federal intragovernmental partners. HHS must foster public trust and improve communication to better lead response and recovery in future PHEs.

Ensuring the Safety, Effectiveness, and Availability of Food and Drug Administration-Regulated Products

HHS's Food and Drug Administration (FDA) regulates crucial consumer products, including human and veterinary drugs, biological products, medical devices, food, cosmetics, products that emit radiation, tobacco, and infant formula. Fifteen cents of every dollar American consumers spend goes to these FDA-regulated products. Reliance on overseas manufacturing, increasingly complex supply chains, novel threats from cyberattacks and other security vulnerabilities, and PHE-related disruptions complicate FDA's mission. FDA must account for these threats and ensure the safety, effectiveness, quality, security, and availability of FDA-regulated products.

- Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries
- Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices
- Toolkit: Insights for Communities From OIG's Historical Work on Emergency Response
- The Food and Drug Administration's Foreign
 For-Cause Drug Inspection Program Can Be
 Improved To Protect the Nation's Drug Supply



2 | Ensuring the Financial Integrity of HHS Programs

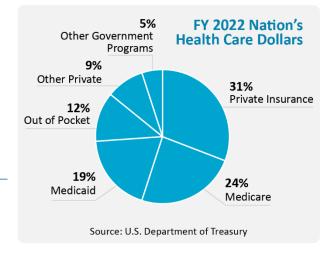
Elements of the Challenge

- Preventing, reducing, and recovering improper payments
- Protecting programs from fraud, waste, and abuse
- Controlling costs by ensuring prudent payments
- Monitoring and reporting on the integrity of HHS financial management

Given the \$2.4 trillion investment in the HHS budget for fiscal year (FY) 2022 and the critical importance of the programs that HHS funds, the Department must work to ensure sound stewardship and combat fraud, waste, and abuse.

Preventing, Reducing, and **Recovering Improper Payments**

In FY 2022, improper payments for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) were estimated at \$131.6 billion. Improper payments duplicate



other payments, fund ineligible services, enrich ineligible providers, cover care for ineligible recipients, or violate other program rules.

- Within the Medicare fee-for-service program, reducing improper payments remains a challenge despite the Centers for Medicare & Medicaid Services' (CMS's) efforts targeting longstanding areas of concern, such as hospice, home health, hospital outpatient, and skilled nursing facility care. Emerging areas of concern, such as aberrantly high-billing labs, upcoded hospital stays to increase reimbursement, and genetic testing, also require attention.
- In the Medicaid program, HHS estimated that the FY 2022 improper payment rate exceeded 15 percent of all payments. Exacerbating Medicaid's challenges, the end of the COVID-19 PHE triggered Medicaid and CHIP eligibility changes that could impact millions of people. States' Medicaid enrollment and renewal processes must meet Federal statutory and regulatory requirements. CMS has an oversight responsibility to ensure that these programs serve and maintain coverage for eligible beneficiaries. Correcting eligibility errors and recouping overpayments from State Medicaid agencies could be BillingStat particularly challenging.

* Sectional Service

HHS also disburses taxpayer dollars via grants and contracts. The Department must provide guidance
and up-to-date policies to inform grant recipients and subrecipients on financial management, internal
controls, and Federal and Departmental Regulations. This includes ensuring sufficient visibility into
subrecipients' use of grant funds to ensure grants are being used for their intended purpose. For
contracts, HHS needs to continue its efforts to improve the contract management and closeout
processes.

Protecting Programs From Fraud, Waste, and Abuse

The Department must prevent, identify, and remedy fraud, waste, and abuse to ensure that taxpayer money serves important program goals and is not diverted for inappropriate, unauthorized, or illegal purposes. The Department must enhance oversight and internal controls to guard against fraud schemes, including embezzlement and theft. Novel fraud schemes, <u>such as scams that use social media to offer fake grants</u>, increase the need for vigilance.

Suspension and debarment programs promote integrity for Federal grants and contracts by ensuring that the Federal Government does business only with responsible people. HHS has improved its suspension and debarment programs by offering outreach, training, and guidance, but additional efforts are needed.

Controlling Costs by Ensuring Prudent Payments

HHS must assess its payment policies, including identifying problematic policies that create perverse incentives for providers or impede patients' access to needed care. To the extent feasible under current law, CMS should establish prudent payment policies that control costs and promote appropriate utilization. Prescription drugs are one area in which policymakers seek to reduce spending and increase coverage. The Inflation Reduction Act requires the Department to implement certain complex new authorities, including negotiating prices for certain high-expenditure Medicare drugs. The Department announced in August 2023 the first 10 drugs subject to negotiation.

Monitoring and Reporting on the Integrity of HHS Financial Management

Within HHS, deficiencies persist in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems that could compromise financial management. Although the Department has taken steps to improve its financial systems, it must take additional actions to address and resolve these issues, including continuing efforts to control user access, ensuring proper approval and documentation of supporting system changes, and ensuring appropriate segregation of duties.



- CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to \$888 Million in Improper Payments
- HHS's Suspension and Debarment Program
 Helped Safeguard Federal Funding, But
 Opportunities for Improvement Exist
- Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States
- <u>UPICs Hold Promise To Enhance Program</u>
 <u>Integrity Across Medicare and Medicaid, But Challenges Remain</u>

- Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks
- <u>Technical Assistance Brief: Implementation of</u>
 Inflation-Indexed Rebates for Part B Drugs
- Medicare Could Have Saved up to \$216 Million
 Over 5 Years if Program Safeguards Had
 Prevented At-Risk Payments for Definitive Drug
 Testing Services
- Trend Toward More Expensive Inpatient
 Hospital Stays in Medicare Emerged Before
 COVID-19 and Warrants Further Scrutiny

3 | Improving Outcomes in Medicare and Medicaid

Elements of the Challenge

- Combating fraud, waste, and abuse
- · Improving quality and safety in nursing homes
- Strengthening oversight of managed care programs
- Fostering equitable access to high-quality care

More than 147 million American seniors, individuals with disabilities, people in low-income households, and individuals with end-stage renal disease and other complex health needs rely on Medicare and Medicaid, so HHS must ensure that these programs deliver high-quality care without disparate outcomes or barriers to access.

Combating Fraud, Waste, and Abuse

Minimizing fraud, waste, and abuse is critical to helping Medicare and Medicaid programs deliver quality to enrollees and value to taxpayers. HHS must focus on fraud prevention (e.g., provider enrollment screening and revalidation), detection (e.g., claims and other data analysis), and enforcement to recover misspent funds, protect patients from harm, and hold wrongdoers accountable. The Department must remain vigilant to protect Medicare and Medicaid programs from fraud, waste, and abuse across all service and provider types, but especially those in high-risk areas, such as durable medical equipment, home health, hospice, genetic testing, treatment for substance use disorder, COVID-19 test billing, and medical identity theft. Different CMS programs (e.g., managed care, traditional Medicare, value-based care models) have different risks because they pay for services or coverage differently. As HHS revises payment policies and incentives, it must anticipate and guard against exploitation of specific payment designs.

Payment Incentive Risk Areas

Traditional Fee-for-Service:

- Inappropriate increased utilization
- Selection of more expensive services than needed
- Improper patient steering

Managed Care

- Denying care
- Discriminating against patients who require costly care and services
- Manipulating/falsifying risk adjustment data

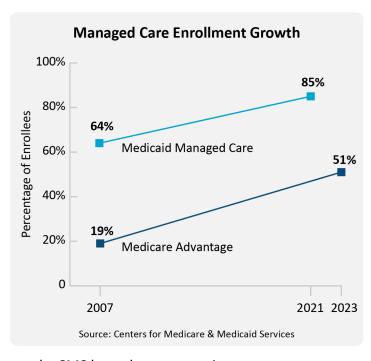
Improving Quality and Safety in Nursing Homes

Nursing home residents deserve safe, high-quality care, yet improving nursing homes remains one of the most complex and intransigent challenges facing the American health care system. The unprecedented COVID-19 pandemic had widespread negative effects across the health care system. It posed novel challenges for nursing home staff, residents, and families, and highlighted longstanding problems in areas such as emergency preparedness and infection control; staffing shortages; frontline oversight by CMS and State survey agencies; and health disparities based on race, ethnicity, and geography.

HHS must continue to focus on improving nursing home performance, including ensuring sufficient staffing to meet residents' needs, expanding transparency of private equity and other ownership information to better understand linkages to quality of care, and bolstering emergency preparedness and infection control. The Department must continue to take meaningful steps to foster safe, high-quality, dignified care for residents in areas such as chemical restraints, facility-initiated discharges, and preventing abuse and neglect. Finally, the Department must remain attentive to strengthening the effectiveness of State survey agency performance and the response to poor-performing nursing homes, such as through the Special Focus Facility Program. Improving nursing home care will require partnerships and sustained commitment from Government and private stakeholders to achieve positive change.

Strengthening Oversight of Managed Care Programs

As managed care continues to expand, now covering more than half of Medicare enrollees and more than 80 percent of Medicaid enrollees, HHS must ensure that managed care operates effectively and efficiently. The Medicare Advantage program suffers when Medicare Advantage organizations claim additional government payments by making their enrollees appear sicker than they might be or when plans avoid costs by denying care that would otherwise be covered by Medicare. CMS must improve its oversight, including of chart reviews and health risk assessments conducted by plans, to ensure accurate risk-adjusted payments that truly reflect enrollees' health status. CMS must also improve its oversight of Medicare and Medicaid managed care to reduce inappropriate prior authorization and payment



denials that serve plan profits over enrollees' health. Recently, CMS has taken steps to increase transparency and improve the information Medicare enrollees can access about Medicare Advantage organizations' prior

authorization and coverage decisions, and it began phasing in updates to the Medicare Advantage risk adjustment model to improve the accuracy of Medicare Advantage.

Fostering Equitable Access to High-Quality Care

Disparities in access and quality of care and in health outcomes persist for Medicare and Medicaid enrollees in some geographic areas, members of some racial and ethnic groups, and individuals with intellectual and physical disabilities. Disparities may be even more pronounced for access to high-quality prenatal care, mental health services, and treatment for substance use disorder. During the COVID-19 PHE, Congress temporarily expanded access to telehealth for Medicare enrollees, resulting in a dramatic increase in use of telehealth. However, telehealth use varied greatly among enrollees in different geographic areas and among certain demographic groups. As the Department implements new telehealth policies, it must balance concerns about issues such as access, quality of care, health equity, privacy and security, and program integrity. As HHS works to reduce health disparities, it must improve the accuracy of relevant data to help measure and facilitate progress in reducing disparities.

- Oversight of Managed Care for Medicare and Medicaid
- Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS
- High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care
- Some Medicare Advantage Organization
 Denials of Prior Authorization Requests Raise
 Concerns About Beneficiary Access to
 Medically Necessary Care
- CMS Should Take Further Action To Address
 States With Poor Performance in Conducting
 Nursing Home Surveys



4 | Protecting HHS Beneficiaries

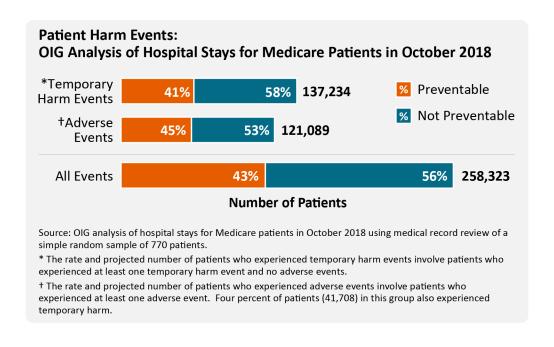
Elements of the Challenge

- Ensuring safety and quality in Federal health care programs
- Protecting the health and safety of children
- Preventing abuse and neglect

HHS programs provide and/or fund critical health care, child care, and educational services for diverse populations in hospitals, clinics, child care facilities, shelters, nursing homes, and peoples' own homes. Ensuring that intended beneficiaries receive appropriate services that meet standards for quality, are free from abuse or neglect, and do not experience preventable harm represents a major challenge for the Department.

Ensuring Safety and Quality in Federal Health Care Programs

Federal health care programs must deliver care that meets quality and safety standards and that intended beneficiaries can access without undue burden or disparities. Although HHS has made progress, more work remains to improve access to and quality of all types of care. Too often, health care results in patient harm, much of which is preventable.



Protecting the Health and Safety of Children

In addition to health care, HHS operates or funds programs that provide child care, education, and residential care to many children, such as children living in foster care and children in the Unaccompanied Children (UC) Program. The Administration for Children and Families should work with States to increase compliance with Federal requirements to protect children in foster care from human trafficking. Unaccompanied children who enter the United States without lawful immigration status are referred to the custody of the Office of Refugee Resettlement (ORR). Most children are released from ORR care to a sponsor, usually a parent or other family member. HHS strives to limit children's time in ORR care while ensuring safe and appropriate release to vetted sponsors.

For children who remain in ORR care, the Department must ensure that UC Program-funded facilities meet all health and safety requirements and provide adequate medical and mental health care. HHS must continue to enhance efforts to ensure that all individuals with access to children have passed required background checks.

Preventing Abuse and Neglect

Thousands of HHS-funded providers hold positions of trust that bring them into close contact with individuals, often behind closed doors and at especially vulnerable times. Most providers earn this trust and work hard to serve people well. However, some providers harm people, and the Department must better protect those enrolled in its programs from abuse and neglect. The Indian Health Service recently initiated extensive measures to protect patients from sexual predators after an Indian Health Service pediatrician went to prison for sexually assaulting boys he treated as patients. These measures reflect meaningful progress, but better attention to protecting people of all ages at risk for abuse and neglect in all care settings is needed.

Thoroughly vetting providers and staff by using background checks helps prevent potential predators from gaining access to victims in Federal programs. The Department must ensure adequate background checks in HHS-funded child care programs and health care settings.

Although awareness may be highest in pediatric settings and nursing homes, people in all care settings are at risk of abuse and neglect. Identifying and reporting abuse and neglect is important but may be particularly challenging in non-facility settings, such as home and community-based services or group homes. All States have enacted mandatory reporting laws that require professionals, such as teachers or nursing home staff, to report suspected abuse or neglect targeting certain individuals, but more must be done to help victims and hold wrongdoers accountable.

States and other partners should use claims data to better identify unreported abuse and neglect, and CMS should compile a list of diagnosis codes that indicate potential abuse or neglect, conduct periodic data extracts, and encourage States to better use data to facilitate compliance with mandatory reporting laws.

CMS should ensure that its reporting requirements sufficiently protect individuals in all care settings and are adequately enforced. Protecting people from abuse and neglect is a critical responsibility that requires attention and cooperation from all stakeholders.

- Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018
- The Office of Refugee Resettlement Needs To Improve Its Oversight Related to the Placement and Transfer of Unaccompanied Children
- The Office of Refugee Resettlement Needs To Improve Its Practices for Background Checks During Influxes
- Toolkit: Insights from OIG's Work on the Office of Refugee Resettlement's Efforts To Care for Unaccompanied Children
- Medicaid Data Can Be Used To Identify
 Instances of Potential Child Abuse or Neglect

- All Six States Reviewed Had Partially
 Implemented New Criminal Background Check
 Requirements for Childcare Providers, and Five of the States Anticipate Full Implementation by Fiscal Year 2020
- In Five States, There Was No Evidence That Many Children in Foster Care Had a Screening for Sex Trafficking When They Returned After Going Missing
- A Resource Guide for Using Diagnosis Codes in Health Insurance Claims To Help Identify Unreported Abuse or Neglect

5 | Securing Data and Technology

Element of the Challenge

Improving cybersecurity for HHS programs, related industry sectors, and individuals

HHS faces persistent cybersecurity threats that exacerbate the challenges associated with data and technologies used to carry out the Department's vital health and human service missions. The large scale of HHS's mission and information technology environments requires that the Department simultaneously address a range of cybersecurity risks along with the specific data and technology needs for each Operating Division/Staff Division (OpDiv/StaffDiv) or program.

cybersecurity threats that exacerbate the challenges associated with data and technologies used to carry out the Department's vital health and human service missions.

Improving Cybersecurity for HHS Programs, Related Industry Sectors, and Individuals

Cyberattacks and related threats can imperil critical HHS operations and programs, potentially compromising the health and welfare of individuals HHS serves. Disparate organizational approaches to cybersecurity that vary by OpDiv/StaffDiv within the Department and across the Government complicate HHS's preparedness efforts to prevent or respond to cybersecurity risks. Improving cybersecurity posture requires significant resource investments and cultural and organizational change across HHS. The Department must ensure that its agencies and programs employ a risk-based approach to identifying and implementing information system security solutions to protect technology and data.

Comprehensive cybersecurity solutions must be implemented not just within the Department but also by the thousands of HHS contractors, grantees, and other external entities. For many HHS programs, effective cybersecurity will depend on these multiple parties implementing comprehensive security solutions that mitigate cyber threats specific to their operations. Protecting technology and data also requires broader efforts beyond implementing technical cybersecurity fixes, such as establishing clear expectations; modernizing program rules; and conducting effective oversight of the Department's contractors, grantees, and other external entities.

HHS must also address significant cybersecurity threats for sectors it oversees. For example, the health care industry remains a prime target for cyberattacks. Bad actors continue to leverage the threat of interrupting patient care to extract ransoms or other value from health care entities. The diffuse nature of HHS cybersecurity authorities and responsibilities complicates response efforts. Some HHS OpDivs/StaffDivs have limited or no authority or expertise to address cybersecurity risks affecting sectors they oversee. Besides HHS, other Federal departments, such as Federal law enforcement and the Department of Homeland Security Cybersecurity and Infrastructure Security Agency, share cybersecurity responsibilities, adding coordination and communication challenges.

To address these challenges, the Department must lead a network of Federal agencies to improve the cybersecurity of the health care and public health sectors. HHS has employed public-private partnerships to improve threat communication with industry partners, but challenges remain that the Department has limited tools to address, including the industry's reliance on legacy technology and workforce challenges.

New approaches to delivering health care, such as expansion of telehealth and remote patient monitoring, can improve access to and quality of care while greater provider interconnectivity can enhance care coordination, but HHS must identify and address the cybersecurity risks associated with their use. As cybersecurity threats and potential targets increase, HHS must maintain vigilance, expeditiously address vulnerabilities, and help the health care industry adapt.

The Department must also work to protect the privacy of sensitive individual data replete throughout the health care system. HHS's actions to enforce the decades-old Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and HIPAA Security Rule may not be sufficient to address contemporary privacy concerns or changes in how patient information is collected and used. The Department must adapt as privacy and security needs evolve and provide guidance for patients and providers.

- The Centers for Medicare & Medicaid Services
 Should Improve Preventative and Detective
 Controls To More Effectively Mitigate the Risk of Compromise
- The IHS Telehealth System Was Deployed
 Without Some Required Cybersecurity Controls
- Maryland MMIS and E&E System Security Controls Were Partially Effective and Improvements Are Needed

- Michigan MMIS and E&E Systems Security
 Controls Were Generally Effective, but Some
 Improvements Are Needed
- Massachusetts MMIS and E&E System Security Controls Were Generally Effective, but Some Improvements Are Needed

Conclusion

Careful attention to these top management challenges will help the Department achieve its crucial mission to manage taxpayer dollars responsibly, safeguard public health, and deliver highquality care and services.

Stay In Touch





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Report Fraud, Waste, and Abuse

OIG Hotline Operations accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS programs. Hotline tips are incredibly valuable, and we appreciate your efforts to help us stamp out fraud, waste, and abuse.



TIPS.HHS.GOV

Phone: 1-800-447-8477

TTY: 1-800-377-4950

Who Can Report?

Anyone who suspects fraud, waste, and abuse should report their concerns to the OIG Hotline. OIG addresses complaints about misconduct and mismanagement in HHS programs, fraudulent claims submitted to Federal health care programs such as Medicare, abuse or neglect in nursing homes, and many more. Learn more about complaints OIG investigates.

How Does it Help?

Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

Who is Protected?

Anyone may request confidentiality. The Privacy Act, the Inspector General Act, and other applicable laws protect complainants. The Inspector General Act of 1978 states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.

