(F) A detailed summary of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(G) A detailed summary of the device technical parameters;

(H) Where appropriate, validated methods and instructions for reprocessing of any reusable components;

(I) The following statement, prominently placed: ''Warning: ECT device use may be associated with: disorientation, confusion, and memory problems''; and

(J) Absent performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of 3 months, the following statement, prominently placed: ''Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.''

(ix) Patient labeling must be provided and include:

(A) Relevant contraindications, warnings, precautions;

(B) A summation of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(C) Information on how the device operates and the typical course of treatment;

(D) The potential benefits;

(E) Alternative treatments;

(F) The following statement, prominently placed: ''Warning: ECT device use may be associated with: Disorientation, confusion, and memory problems'';

(G) Absent performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of 3 months, the following statement, prominently placed: ''Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated''; and

(H) The following statements on known risks of ECT, absent performance data demonstrating that these risks do not apply:

(*1*) ECT treatment may be associated with disorientation, confusion and memory loss, including short-term (anterograde) and long-term (autobiographical) memory loss following treatment. Based on the majority of clinical evidence, these side effects tend to go away within a few days to a few months after the last treatment with ECT. Although the incidence of permanent cognitive memory loss was not supported by the clinical literature, some patients have reported a permanent loss of memories of personal life events (*i.e.,* autobiographical memory);

(*2*) Patients treated with ECT may experience manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) or a worsening of the psychiatric symptoms they are being treated for; and

(*3*) The physical risks of ECT may include the following (in order of frequency of occurrence):

(*i*) Pain/somatic discomfort (including headache, muscle soreness, and nausea);

(*ii*) Skin burns;

(*iii*) Physical trauma (including fractures, contusions, injury from falls, dental and oral injury);

(*iv*) Prolonged or delayed onset seizures;

(*v*) Pulmonary complications (hypoxemia, hypoventilation, aspiration, upper-airway obstruction);

(*vi*) Cardiovascular complications (cardiac arrhythmias, heart attack, high or low blood pressure, and stroke); and

(*vii*) Death.

(2) *Classification:* Class III (premarket approval) for the following intended uses: schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, and catatonia or a severe MDE associated with MDD or BPD in:

(i) Patients under 13 years or

(ii) Patients 13 years and older who are not treatment-resistant or who do not require a rapid response due to the severity of their psychiatric or medical condition.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before March 26, 2019, for any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 26, 2019, been found to be substantially equivalent to any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: December 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27809 Filed 12–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 2

[Docket No. USPC–2018–03]

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the United States and District of Columbia Codes

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The United States Parole Commission is revising a rule that authorizes the Chairman to delegate a Commissioner to conduct parole hearings. This procedural change will permit a Commissioner to conduct parole hearings and vote on the decision resulting from the proceeding, providing for a more efficient use of agency resources.

DATES: This regulation is effective December 26, 2018.

FOR FURTHER INFORMATION CONTACT: Helen H. Krapels, General Counsel, U.S. Parole Commission, 90 K Street NE, Third Floor, Washington, DC 20530, telephone (202) 346–7030. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: The U.S. Parole Commission is revising its rule at 28 CFR 2.59 that authorizes the Chairman to delegate a Commissioner to act as a Hearing Examiner, but disqualifies the Commissioner from voting in the case as a Commissioner during the proceeding. The authority of U.S. Parole Commissioners to conduct hearings and make decisions for offenders under the Commission's jurisdiction is inherent in the Commission's authority under 18 U.S.C. 4203. Moreover, 18 U.S.C. 4203(c)(1) specifically authorizes the Commission to delegate to any Commissioner or commissioners the powers to grant or deny parole, impose conditions on an order granting parole, modify or revoke parole, etc. With the potential winding-up of the agency in two years, having

Commissioners conduct parole hearings and also vote in the same proceeding is a more efficient use of resources to balance the agency's workload and promote continuity of the agency's business. This is a procedural change only, and will not implicate the merits of any prisoner's case for parole or affect the way in which hearings are conducted. Hence, notice and public comment is not required.

The revised rule will take effect on December 26, 2018.

Executive Orders 12866 and 13563

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulation Planning and Review,'' section 1(b), Principles of Regulation, and in accordance with Executive Order 13565, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation. The Commission has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications requiring a Federalism Assessment.

Regulatory Flexibility Act

This rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local, or tribal governments, or the private sector, to spend $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

This rule is not a ''major rule'' as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 Subtitle E—Congressional Review Act, now codified at 5 U.S.C. 804(2). The rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability of United States-based companies to compete with foreign-based companies. Moreover, this is a rule of agency practice or procedure that does not substantially affect the rights or obligations of non-agency parties, and does not come within the meaning of the term ''rule'' as used in Section 804(3)(C), now codified at 5 U.S.C. 804(3)(C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and parole.

The Final Rule

Accordingly, the U. S. Parole Commission amends 28 CFR part 2 as follows:

PART 2—[AMENDED]

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

■ 2. Revise § 2.59 to read as follows:

§ 2.59 Delegation to Commissioners.

There is hereby delegated to Commissioners the authority to conduct hearings, with the Commissioner's consent, and the powers enumerated in 18 U.S.C. 4203(b) to grant or deny parole or mandatory release, impose reasonable conditions of parole or mandatory release, modify or revoke parole or mandatory release.

Dated: December 18, 2018.

Patricia K. Cushwa,

Chairman (Acting), U.S. Parole Commission.

[FR Doc. 2018–27803 Filed 12–21–18; 8:45 am]

BILLING CODE 4410–31–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 006–2018]

Privacy Act of 1974; Implementation

AGENCY: Office of the Inspector General, United States Department of Justice.

ACTION: Final rule.

SUMMARY: The Office of the Inspector General (OIG), a component within the United States Department of Justice (DOJ or Department), is finalizing its Privacy Act exemption regulations for the system of records titled, ''Data Analytics Program Records System,'' JUSTICE/OIG–006, which were published as a Notice of Proposed Rulemaking (NPRM) on March 28, 2018. Specifically, the Department's regulations will exempt the records maintained in JUSTICE/OIG–006 from one or more provisions of the Privacy Act and implement other administrative changes. The exemptions are necessary to avoid interference with the law enforcement functions and responsibilities of OIG. The Department received 21 comments on the NPRM, none of which addressed the substance of the proposed Privacy Act exemption regulations for JUSTICE/OIG–006.

DATES: This final rule is effective January 25, 2019.

FOR FURTHER INFORMATION CONTACT: Jonathan M. Malis, General Counsel, Office of the Inspector General, Department of Justice, 950 Pennsylvania Avenue NW, Washington, DC 20530, phone: (202) 514–3435.

SUPPLEMENTARY INFORMATION: Pursuant to the Inspector General Act of 1978, as amended, Inspectors General, including the DOJ Inspector General, are responsible for conducting, supervising, and coordinating audits and investigations to recognize and mitigate fraud, waste, and abuse by programs and operations of the Federal agency for which their office is established. On March 28, 2018, OIG published a System of Records Notice (SORN) for its system of records titled, ''Data Analytics Program Records System,'' JUSTICE/OIG–006, 83 FR 13309 (March 28, 2018), for the records collected to implement its data analytics (DA) program. The DA program will assist with the performance of OIG audits, investigations, and reviews, and accommodate the requirements of the Digital Accountability and Transparency Act of 2014, Public Law 113–101, 128 Stat. 1146. Specifically, the DA program will provide OIG: timely insights from the data already stored in DOJ databases that OIG has legal authorization to access and maintain; the ability to monitor and analyze data for patterns and correlations that signal wasteful, fraudulent, or abusive activities impacting Department performance and operations; the ability to find, acquire, extract, manipulate, analyze, connect, and visualize data; the capability to manage vast amounts of data; the ability to identify significant information that can improve decision quality; and the ability to mitigate risk of waste, fraud, and abuse.