March 17, 2014

Centers for Medicare and Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development  
Attention: Document Identifier CMS-R-53 / OMB: 0938-0429  
Control Number Ill, Room C4–26–05  
7500 Security Boulevard  
Baltimore, Maryland 21244–1850.

RE:  Comments on CMS-R-53; OCN: 0938-0429 (CMS-10398; OCN:0938-1148)

I write on behalf of the Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS) to comment on the request for comment on CMS-R-53 (OCN: 0938-0429)1 regarding “Imposition of Cost Sharing Charges under Medicaid and Supporting Regulations” (Notice).2 We appreciate the opportunity to provide comments.

The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children’s Health Insurance Program, and any other health care program funded (in whole or part) by CMS. In particular, the TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (AI/ANs) under these Federal health care programs, including through providers operating under the health programs of the Indian Health Service, Indian Tribes, tribal organizations and urban Indian organizations (referred to as Indian Health Care Providers or I/T/Us).

BACKGROUND

The Notice indicates that the purpose of CMS’s intention to collect information pursuant to this Notice is –

To ensure that States impose nominal cost sharing charges upon categorically and medically needy individuals as allowed by law and implementing regulations. States must identify in their State plan the service for which the charge is made, the amount of the charge, the basis for determining the charge, the basis for determining whether an

1 The document reference numbers appear to be transitioning to (CMS-10398; OCN:0938-1148).
2 79 Fed Reg 8971. The supporting documents issued along with the Federal Register notice are included in references to the Notice.
individual is unable to pay the charge and the in which the individuals will be identified to providers, and the procedures for implementing and enforcing the exclusions from cost sharing.

As indicated in the Notice, the current authority provided to States to impose cost sharing on certain Medicaid enrollees and services as well as the restrictions on States from imposing cost sharing on certain Medicaid enrollees and services was developed over decades. In 1972, States were permitted to impose cost sharing on all services provided to medically needy individuals and on optional services provided to the categorically needy. In 1982, as a result of enactment of the Tax Equity and Fiscal Responsibility Act (TEFRA), cost sharing applications were broadened for certain populations and services, and cost sharing protections were established for other populations and services. For example, TEFRA removed the restrictions on cost sharing for services furnished to the categorically needy. In addition, TEFRA established requirements for excluding “certain institutionalized individuals” from cost sharing and prevented cost sharing requirements to be imposed for “emergency and family planning services.”

The TTAG is particularly interested in reporting requirements under consideration here that are designed to ensure compliance by States with enforcing the exclusions from cost sharing found in Section 447.53(b). Of particular importance to TTAG, under Section 447.53(b)(6), cost sharing exclusions are to “apply to items and services furnished to an Indian directly by an Indian health care provider or through referral under contract health services.” Specifically, States are required to do the following: (1) set forth procedures on how recipients excluded from cost sharing would be identified to providers; and (2) specify in its State plan the procedures for implementing and enforcing the exclusions from cost sharing found in Section 447.53(b).

CMS considered allowing States – rather than requiring them to document compliance – to merely provide assurances that a State has complied with the regulatory requirements. CMS rejected this option, commenting –

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3 On January 1, 2014, Section 447.53 and related sections were restructured.
5 Indians are defined at Section 447.51 (as revised effective January 1, 2014) as, “Indian means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual: (1) Is a member of a Federally-recognized Indian tribe; (2) Resides in an urban center and meets one or more of the following four criteria: (i) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member; (ii) Is an Eskimo or Aleut or other Alaska Native; (iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or (iv) Is determined to be an Indian under regulations promulgated by the Secretary; (3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or (4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.”
Given the numerous possibilities under the cost-sharing rules, it would not be enough simply to obtain assurances from the State that say these rules are being followed. Within these rules are a variety of options and program alternatives that must be recorded within the framework of the State’s plan, in order to ensure compliance.

The Notice also indicates that States are required to establish and report on the procedures employed to meet program cost sharing requirements, but CMS provides States significant flexibility in how a State meets the requirements. The Notice reads:

Although States are required to specify their procedures for implementing and enforcing the statutory exclusions from cost sharing, no Federal guidelines have been adopted that must be followed by States. We believe that this provision gives States flexibility to accommodate the substantive differences in their systems…

In our comments below on this Notice, the TTAG focuses on “the procedures for implementing and enforcing the exclusions from cost sharing” and will do so in regard to the Indian-specific protections which apply to American Indians and Alaska Natives (AI/ANs). In addition, our comments and recommendations recognize the intention of CMS to continue to provide to States flexibility in how States implement the requirements.

ANALYSIS

Enacted in 2009, Section 5006(a)(1)(A) of the American Recovery and Reinvestment Act (ARRA) eliminates cost sharing under Medicaid for AI/ANs who are furnished any item or service directly by the IHS, an Indian Tribe, Tribal Organization, or Urban Indian Organization (referred to collectively as Indian Health Care Providers or I/T/U) or through referral under Contract Health Services (CHS). This provision also prohibits plan issuers from reducing payments to any such entity by the amount of any cost sharing that would be due but for the exemption. Combined, these provisions provide an important protection for both AI/ANs and I/T/U providers by facilitating access to services, promoting continuity of care, and advancing provider choice.

CMS Guidance to States

The final rule implementing the ARRA Section 5006(a)(1)(A) protections was issued by CMS on July 15, 2013.6 The regulations implementing ARRA Section 5006(a)(1)(A) became effective on January 1, 2014. Guidance to States on implementation of the rule is provided by CMS in the preamble to the proposed rule7 (issued on January 22, 2013) and in the

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6 CMS-2334-F, 78 Fed Reg 42160.
7 78 Fed Reg 4594.
preamble to the final rule. While maintaining flexibility for States, the guidance provided by CMS clarifies a number of points and facilitates the successful implementation of the cost sharing protections. For example, CMS provided the following guidance in the preamble to the proposed rule (CMS-2334-P) on how to comply with the cost sharing protections for services provided under referral by an Indian Health Care Provider and whether paper referrals would be required:

Because no formal paper trail may occur for the Medicaid agency to establish that a service has been delivered based on a referral under contract health services, we propose a broad definition of the cost sharing exemption for Indians. We propose that those Indians who are currently receiving or have ever received an item or service furnished by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (I/T/U) or through referral under contract health services are exempt from all cost sharing. With this clarification the Medicaid agency would not have to know if a particular service was provided based on contract health service referral and would ensure that Indians who should be exempt on such bases will not be inadvertently charged cost sharing. States could implement this exemption by using claims payment data to identify Indians who have accessed services from an I/T/U, or as many states have done, by requesting that eligible Indians submit a letter, available through the Indian Health Service, designating them as Indians who have utilized such services and are, therefore, exempt from Medicaid cost sharing.”

We agree with the assessment provided by CMS and strongly support the statement that “Indians who are currently receiving or have ever received an item or service furnished by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (I/T/U) or through referral under contract health services are exempt from all cost sharing.” We believe the explanation for this interpretation found in the preamble to the proposed rule is accurate in its assessment of the issues that face State Medicaid programs absent this rule.

In addition, in the preamble to the final rule (CMS-2334-F), CMS provided the following guidance on approaches to verifying eligibility for the Indian-specific cost sharing protections:

*Comment:* A few commenters suggested states should have broad latitude in applying verification procedures to exempt AI/ANs who are eligible for or currently or have ever received a service from an Indian provider or

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8 78 Fed Reg 4660.
through referral under contract health services (CHS) from premiums and cost sharing respectively, and that procedures that create the least burden on individuals, including electronic processes, be employed by states. They recommended that self-attestation of status for the AI/AN cost sharing exemption be permitted, that if verification is required that electronic data matching should be used to the maximum extent possible, and that we provide a list of possible documents which states could use when electronic verification is not available.

Response: There are no specific federal requirements regarding the process for verifying premiums and cost sharing exemptions for AI/ANs. States have flexibility to establish their own processes for verifying who is eligible to receive or has ever received a service from an Indian provider or through referral under CHS, including the use of self-attestation, electronic data matches or reasonable paper documentation, as long as the process is not unduly burdensome on AI/ANs.9

As there is no single process mandated for verifying eligibility for premiums and cost sharing exemptions for AI/ANs, the Federally-Facilitated Marketplace (FFM) and States have broad flexibility to establish such standards. For example, CMS reported on a recent All Tribes Call that the FFM for the purpose of verifying AI/AN eligibility for Medicaid cost-sharing exemptions would accept self-attestation by AI/ANs with no additional documentation requirements. States like Oregon have followed this approach and demonstrate the broad flexibility imbedded in this guidance, resulting in approaches that are effective and do not impose unnecessary burdens on enrollees or providers in the process. We are concerned, though, that some States are using the flexibility provided by CMS to simply minimize their efforts in this area and are being lax in establishing effective procedures to guarantee that eligible AI/ANs are receiving these cost sharing protections.

Failures in State Implementation of Indian-specific Cost Sharing Protections

To date, we do not see effective implementation of the Indian-specific cost sharing protections uniformly across the States. Many State eligibility processes and data systems do not appear to be capturing data on who is eligible for the Indian-specific cost sharing protections, and providers are not being informed of who is eligible for the Indian-specific protections. In addition, many AI/ANs are not aware of the cost sharing protections available to them. Because of this, these individuals are not likely to proactively inform a State Medicaid agency of their eligibility or object if cost sharing requirements are imposed on them.

9 79 Fed Reg 92280.
Given that CMS is intending to issue through this Notice a “revision of a currently approved [data] collection” for the purpose of ensuring that States, in part, establish “the procedures for implementing and enforcing the exclusions from cost sharing,” we encourage CMS to take this opportunity to focus particular attention on the protections for American Indians and Alaska Natives that were enacted into law in 2009 and for which final rules were recently promulgated.

RECOMMENDATIONS

TTAG offers the following recommendations to facilitate the successful development of procedures that would effectively implement and enforce the exclusions from cost sharing for certain American Indians and Alaska Natives found in current regulations at 42 CFR § 447.56(x).

1. **We recommend that CMS develop a template (or templates) of procedures that could be adopted by States that would implement and enforce the Indian-specific exclusions from cost sharing.** To prepare such a template (or templates), we encourage CMS to work with Tribal representatives through the TTAG.

   We recognize the intention of CMS to continue to provide flexibility to States in complying with federal requirements pertaining to the imposition of and protection from cost sharing under Medicaid. Given that, we suggest that CMS offer any templates developed as options to States. States would be free to adopt the offered template or could develop alternative approaches. The development of the template, though, would likely result in expediting implementation of approaches that are effective in providing the protections to AI/ANs while minimizing the burden placed on States, providers, health plans and enrollees to achieve this result.

2. **We recommend that the template incorporate an option for self-attestation of eligibility as an American Indian or Alaska Native.** As indicated by CMS above, “States have flexibility to establish their own processes for verifying who is eligible to receive or has ever received a service from an Indian provider or through referral under CHS, including the use of self-attestation.” Self-attestation would streamline the process for eligibility determinations and eliminate the likelihood that paperwork requirements would impede an individual from accessing the protections for which he or she is eligible.

3. **We recommend that State Medicaid information systems be modified to capture an identifier for persons determined to be eligible for the Indian-specific cost-sharing protections.**

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10 79 Fed Reg 8971.
Under the leadership of the California Rural Indian Health Board (CRIHB), and with the assistance of the TTAG Data Subcommittee, efforts are underway with Arun Natarajan of the Center for Medicaid and CHIP Services (CMCS) and the CMCS Division of Tribal Affairs to incorporate in the Transformed Medicaid Statistical Information System a data element that captures whether or not Medicaid enrollees are “Indians who are currently receiving or have ever received an item or service furnished by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (I/T/U) or through referral under contract health services are exempt from all cost sharing”. We encourage CMS to continue and ultimately complete this initiative, including assisting States with adoption of the new functionality.

4. We recommend inclusion in the template of a mechanism for electronic data matching to proactively identify persons eligible for the Indian-specific protections.

Given the lack of familiarity by AI/AN enrollees – as well as possibly State Medicaid agency case workers – with the Indian-specific cost sharing protections, incorporating a proactive mechanism into the procedures implementing the cost sharing protections would heighten the number of eligible persons who ultimately receive the cost sharing protections.

The IHS National Data Warehouse, maintained by IHS but containing information on all persons served by all Indian Health Care Providers, is readily available for use for this purpose. In May of 2013, the Tribal Self-Governance Advisory Committee to IHS (TSGAC) produced a report titled “Enabling Electronic Verification of Eligibility for Indian-specific Benefits and Protections under Medicaid and the Affordable Care Act”\(^1\) that details how this functionality may be established. The IHS concurred with the Tribal recommendations made in the report, which included using the IHS National Data Warehouse for identifying persons eligible for various Indian-specific benefits and protections under Medicaid. The report has also been presented to CMS leadership.

The electronic data matching recommended here would not be a substitute for allowing individuals to independently identify themselves as eligible for the Indian-specific cost sharing protections (including hopefully allowing for self-attestation.) The data matching capability would effectively pre-populate the identifier for new and existing enrollees who have previously accessed an Indian Health Care Provider, thereby identifying a significant number of persons who may otherwise not learn of the protections. In addition, automatically populating a data field in the Medicaid

\(^1\) The TSGAC report may be found on the TSGAC Web site at http://www.tribalselfgov.org/____NEWSGCE/index.html
[Management Information System] will facilitate the use of the data by the State to inform providers and health plans of eligibility for the comprehensive Indian-specific cost sharing protections. This capability would enable real-time verification of eligibility and do so in a manner that is accurate and efficient (i.e., greatly reduces the level of effort required of applicants, tribes and eligibility staff.)

CONCLUSION

Again, we appreciate the opportunity to comment on this Notice. We recognize that some of the recommendations made in this letter may be beyond the restricted scope of a Paperwork Reduction Act Notice. To the extent this is the case, we would appreciate these comments being forwarded to CMS staff that have responsibility for ensuring implementation and conducting oversight of State efforts on this matter.

Please contact Elizabeth McCormick, mmccormick@nihb.org if you would like to discuss the issues addressed in this comment, including establishing a process to incorporate TTAG input into the development of a template.

Sincerely,

Valerie Davidson
Chair, TTAG

Cc: Marilyn Tavenner, Administrator, CMS
    Cindy Mann, Director, Center for Medicaid and Children Services
    Kitty Marx, Director of Tribal Affairs, CMS
    Dr. Yvette Roubideaux, Director, IHS
    Stacy Bohlen, Executive Director, NIHB
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, Announces the Following Meeting

Name: ICD–10 Coordination and Maintenance (CM) Committee meeting.

Time and Date: 9:00 a.m.–5:00 p.m., March 19–20, 2014.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 240 people.

Security Considerations: Due to increased security requirements CMS has instituted stringent procedures for entrance into the building by non-government employees. Attendees will need to present valid government-issued picture identification, and sign-in at the security desk upon entering the building.

Attendees who wish to attend the March 19–20, 2014 ICD–10–CM CM and C&M meeting must submit their name and organization by March 14, 2014, for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting.

Participants who attended previous Coordination and Maintenance meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you wish to attend.

Please register to attend the meeting on-line at: http://www.cms.hhs.gov/app/events/

Please contact Mady Hue [410–786–4510 or Marilu.hue@cms.hhs.gov], for questions about the registration process.

Purpose: The ICD–10 Coordination and Maintenance (CM) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification and ICD–10 Procedure Coding System. Matters To Be Discussed: Tentative agenda items include: March 19–20, 2014.

ICD–10 Topics:

Administration of Dalbavancin Administration of Serselaxin Implantation of Chemotherapeutic Agent Number of Coronary Vessels and Stents Addenda and key updates ICD–10 MS–DRGs Update ICD–10–CM Home Health Conversions ICD–10–CM Diagnosis Topics: Abnormal level of advanced glycation end products in tissues Complications of nervous system devices Complications of urinary devices Encounters for newborns, infant and child health examinations External cause codes for over exertion and repetitive motion Familial Hypercholesterolemia In–Stent Restenosis of Coronary and Peripheral Stent Necrotizing enterocolitis for non newborns Observation and evaluation of newborns for suspected condition not found Oral medicine controlled diabetes mellitus Pediatric topics Pulsatile tinnitus Sesamoid fracture ICD–10–CM Addendum Agenda items are subject to change as priorities dictate.

Note: CMS and NCHS will no longer provide paper copies of handouts for the meeting. Electronic copies of all meeting materials will be posted on the CMS and NCHS Web sites prior to the meeting at http://www.cms.hhs.gov/ICD9Provider DiagnosticCodes/03_meetings.asp TopOfPage and http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

Contact Person for Additional Information: Donna Pickett, Medical Systems Administrator, Classifications and Public Health Data Standards Staff, NCCHS, 3311 Toledo Road, Room 2337, Hyattsville, Maryland 20782, email dfp4@cdc.gov, telephone 301–438–4434 (diagnosis); Mady Hue, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244, email marilu.hue@cms.hhs.gov, telephone 410–786–4510 (procedures).

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker, Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–03245 Filed 2–13–14; 8:45 am]
BILLING CODE 4160–16–P
DATES: Comments on the collection(s) of information must be received by March 17, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:
1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.
2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ___, Room C4–26, 65, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations; Use: The purpose of this collection is to ensure that states impose nominal cost sharing charges upon categorically and medically needy individuals as allowed by law and implementing regulations. States must identify in their state plan the service for which the charge is made, the amount of the charge, the basis for determining the charge, the basis for determining whether an individual is unable to pay the charge and the way in which the individual will be identified to providers, and the procedures for implementing and enforcing the exclusions from cost sharing. The template has been revised and is being released for this 30-day comment period before it is submitted to OMB for review and approval under CMS–10396 (OCN: 0938–1148). Form Number: CMS–R–53 (OCN: 0938–0429); Frequency: Occasionally;Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 10; Total Annual Hours: 50. (For policy questions regarding this collection contact Rebecca Bruno at 415–744–3677).

Marjorie Jones,
Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–02397 Filed 2–13–14; 8:45 am] BILLING CODE 4102–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–21 and –21B]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.
ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notices in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 15, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:
1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.
2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ___, Room C4–26, 65, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in