treated with these TIL along with interleukin-2. At the site of tumor, these TIL destroy tumor either by direct contact or by the secretion of cytokines. Several clinical studies have demonstrated the efficacy of this cancer therapy.

**ADDRESS:** Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Raphe Kantor, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804. Telephone: (301) 496-7735 ext. 247; Facsimile: (301) 402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications. Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NIH on or before October 10, 1995 will be considered. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 26, 1995.

Barbara M. McGarey,
Deputy Director, Office of Technology Transfer.


**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Office of Inspector General (OIG) issues Special Fraud Alerts based on information it obtains concerning particular fraudulent and abusive practices within the health care industry. These Special Fraud Alerts provide the OIG with a means of notifying the industry that we have become aware of certain abusive practices which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate. The alerts also serve as a powerful tool to encourage industry compliance by giving providers an opportunity to examine their own practices.

The Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs. On December 19, 1994, the OIG published in the *Federal Register* the texts of 5 previously-issued Special Fraud Alerts, and announced the intention to publish in the same manner subsequent issuances as a regular part of distribution of these Special Fraud Alerts (59 FR 65372).

The first of these new Special Fraud Alert serves to point out the prevalence of certain types of home health care fraud, including (1) cost report frauds; (2) billing for excessive services or services not rendered; (3) use of unlicensed or untrained staff; (4) falsified plans of care; (5) forged physician signatures on plans of care; and (6) kickbacks that the OIG has uncovered.

The second new Special Fraud Alert, focusing on the provision of medical supplies to nursing facilities, identifies some of the illegal practices that the OIG has recently uncovered. These include (1) the submitting of claims to Part B of Medicare for medical supplies and equipment that are not medically necessary; (2) submitting claims for items that are not provided as claimed; (3) double billings; and (4) paying or receiving kickbacks in exchange for Medicare or Medicaid referrals.

These two issuances are the first in a series of new Special Fraud Alerts being developed by the OIG over the next year to heighten both the public’s and industry’s awareness of fraudulent health care practices. A reprint of both of these Special Fraud Alerts follows.

**II. Special Fraud Alert: Home Health Fraud**

(June 1995)

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the home health industry and identifies some of the illegal practices the OIG has uncovered.

What Is Home Health Care And Who Is Eligible To Receive It?

Medicare’s home health benefit allows people with restricted mobility to remain non-institutionalized and receive needed care at home. Home health services and supplies are typically provided by nurses and aides under a physician-certified plan of care. Medicare will pay for home health services if a beneficiary’s physician certifies that he or she:

- is homebound—i.e., confined to the home except for infrequent or short absences or trips for medical care, and
- requires one or more of the following qualifying services: physical therapy, speech-language pathology, or intermittent skilled nursing.

If a homebound patient requires a qualifying service, Medicare also covers services of medical social workers and certain personal care such as bathing, feeding, and assistance with medications. However, a beneficiary who needs only this type of personal or custodial care does not qualify for the home health benefit.

Fraud and Abuse in the Home Health Industry

Home care is consuming a rapidly increasing portion of the federal health budget. This year, Medicare payments for home health will reach close to $16 billion, up from $3.3 billion in 1990—nearly a five-fold increase. Home health care is particularly vulnerable to fraud and abuse because:
Medicare covers an unlimited number of visits per patient; beneficiaries pay no co-payments except on medical equipment; patients don't receive explanations of benefits (EOBs) for bills submitted for home health services; and there is limited direct medical supervision of home health services provided by non-medical personnel.

The OIG has learned of several types of fraudulent conduct, outlined below, which have or could result in improper Medicare reimbursement for home health services.

False or Fraudulent Claims Relating to the Provision of Home Health Services

The government may prosecute persons who submit or cause false or fraudulent claims for payment to be submitted to the Medicare or Medicaid programs. Examples of false or fraudulent claims include claims for services that were never provided, duplicate claims submitted for the same service, and claims for services to ineligible patients. A claim for a service that a health care provider knows was not medically necessary may also be a fraudulent claim.

Submitting or causing false claims to be submitted to Medicare or Medicaid may subject a person to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. OIG has uncovered the following types of fraudulent claims related to the provision of home health services.

Claims For Home Health Visits That Were Never Made And For Visits To Ineligible Beneficiaries

OIG has uncovered instances where home health agencies are submitting false claims for home health visits. These include:

- Claims for visits not made.
- Claims for visits to beneficiaries not homebound.
- Claims for visits to beneficiaries not requiring a qualifying service.
- Claims for visits not authorized by a physician.

One home health agency billed Medicare for 123 home health visits to a patient who never received a single visit, and submitted claims for beneficiaries who were in an acute care hospital during the period the agency claimed to have provided home visits. Another agency provided a home health aide to a beneficiary so mobile that he volunteered at a local hospital several times a week.

A third agency claimed nearly $26 million during one year in visits that were not made, visits to patients that were not homebound, and visits not authorized by a physician. OIG interviews indicated that beneficiary signatures were forged on visit logs and physician signatures were forged on plans of care. This agency had subcontracted with other entities to provide home health care to its patients, and claimed that the subcontractors falsely documented that visits were made and services were provided.

Medicare permits a home health agency to contract with other organizations, including agencies not certified by Medicare, to provide care to its patients. However, the agency remains liable for all billed services provided by its subcontractors. The use of subcontracted care imposes a duty on home health agencies to monitor the care provided by the subcontractor.

Home health agencies, as well as the physicians who order home health services, are responsible for ensuring the medical necessity of claims submitted to Medicare. A physician who orders unnecessary home health care services may be liable for causing false claims to be submitted by the home health agency, even though the physician does not submit the claim. Furthermore, if agency personnel believe that services ordered by a physician are excessive or otherwise inappropriate, the agency cannot avoid liability for filing improper claims simply because a physician has ordered the services.

Fraud in Annual Cost Report Claims

In addition to submitting claims for specific services, home health agencies submit annual cost reports to Medicare for reimbursement of administrative, overhead and other general costs. For these costs to be allowable, Medicare regulations require that they be (1) reasonable, (2) necessary for the maintenance of the health care entity, and (3) related to patient care. However, the OIG has audited cost reports which include costs for entertainment, travel, lobbying, gifts, and other expenses unrelated to patient care such as luxury automobiles and cruises. One home health agency claimed several million dollars in unallowable costs during one cost reporting year. These included utility and maid service payments for the owner's condominium, golf pro shop expenses, lease payments on a luxury car for the owner's son at college, and payment of cable television fees for the owner's mother.

Medicare also requires home health agencies to disclose in their cost reports the identity of related parties with whom they conduct business, in order to adjust costs that are likely to be inflated by health care providers who self-deal (i.e., purchase goods or services from related companies). A related party issue exists when there is common control or common interest between the provider and the organization with whom it is doing business. OIG has investigated home health agencies which failed to disclose ownership or other relationships with entities with whom they contracted for accounting services, management/consulting services, and medical supplies. These agencies billed Medicare unallowable amounts for marked-up supplies and services.

Paying Or Receiving Kickbacks In Exchange For Medicare or Medicaid Referrals

Kickbacks in exchange for the referral of reimbursable home health services is another type of fraud that OIG has observed. The Medicare program guarantees freedom of choice to its beneficiaries in the selection of health care providers. Because kickbacks violate that principle and also increase the cost of care, they are prohibited under the Medicare and Medicaid programs. Under the anti-kickback statute, it is illegal to knowingly and willfully solicit, receive, offer or pay anything of value to induce, or in return for, referring, recommending or arranging for the furnishing of any item or service payable by Medicare or Medicaid.

OIG is aware of home health providers offering kickbacks to physicians, beneficiaries, hospitals, and rest homes in return for referrals. Kickbacks have taken the following forms:

- Payment of a fee to a physician for each plan of care certified by the physician on behalf of the home health agency.
- Disguising referral fees as salaries by paying referring physicians for services not rendered, or in excess of fair market value for services rendered.
- Offering free services to beneficiaries, including transportation and meals, if they agree to switch home health providers.
- Providing hospitals with discharge planners, home care coordinators, or home care liaisons in order to induce referrals.
- Offering free services, such as 24 hour nursing coverage, to retirement homes or adult congregate living facilities in return for home health referrals.
- Subcontracting with retirement homes or adult congregate living facilities for the provision of home
health services, to induce the facility to make referrals to the agency.
Parties that violate the anti-kickback statute may be criminally prosecuted, and also may be subject to exclusion from the Medicare and Medicaid programs.

Marketing Uncovered Or Unneeded Home Care Services to Beneficiaries

OIG has learned of high pressure sales tactics employed by some agencies in the home health community to maximize their patient population and their profits. These agencies target healthy beneficiaries on the street or in their homes and offer non-covered services, such as grocery shopping or housekeeping, in exchange for Medicare identification numbers. Physicians have also reported that some agencies attempt to pressure them to order unnecessary personal care services by informing them that their patients are requesting these services and will find another physician if their demands are not met.

These abusive marketing practices can result in false claims liability on the part of agencies and/or physicians, and may also constitute illegal kickbacks.

III. Special Fraud Alert: Medical Supplies to Nursing Facilities
(August 1995)

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the provision of medical supplies to nursing facilities and identifies some of the illegal practices that the OIG has uncovered.

How Nursing Facility Benefits are Reimbursed

Many nursing facilities receive reimbursement from Medicare and Medicaid for care and services provided to eligible residents. Under Medicare Part A, skilled nursing facility services are paid on the basis of cost, and compensate the provider for covered nursing stays of a limited length. For Medicare-eligible residents, extended nursing facility stays may be reimbursed by state-administered programs financed in part by Medicaid. Nursing facility residents may be concurrently eligible for benefits under Medicare Part B. These benefits may include payment for medically necessary equipment, prosthetic devices and supplies.

Nursing facilities and their residents have become common targets for fraudulent schemes involving medical supplies. The OIG has become aware of a number of fraudulent arrangements by which medical suppliers profit from inappropriate business dealings, in the name of unwitting nursing facility residents.

Sometimes, nursing facility management and staff also are involved in these schemes.

False or Fraudulent Claims Relating to the Provision of Medical Supplies

The government may prosecute persons who submit or cause the submission of false or fraudulent claims to the Medicare or Medicaid program. Examples of false or fraudulent claims include claims for items that were never provided or were not provided as claimed, duplicate claims submitted for the same item, and claims for items that the supplier knows are not medically necessary.

Submitting or causing false claims to be submitted to Medicare or Medicaid may subject the individual or entity to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. The OIG has uncovered the following types of fraudulent transactions related to the provision of medical supplies to nursing facilities.

Claims for Medical Supplies and Equipment That Are Not Medically Necessary

- Many of the supplies and equipment used in the care of nursing facility residents are provided by the nursing facility and should be reflected in the facility’s Medicare cost report. The OIG has uncovered numerous instances in which suppliers provide the nursing facility with general medical supplies such as tape, adhesive remover, skin creams and syringes, but rather than bill the facility, the supplier submits claims to Medicare Part B. The claims misrepresent that the items are medically necessary for individual beneficiaries and therefore reimbursable under Part B.

- For example, one supplier billed Part B for an “oral/nasal hygiene program” which consisted of supplies, such as saline solution, latex gloves and cotton swabs, marketed as prepackaged kits. Upon investigation, the OIG determined that these items, which were shipped to the facility in bulk quantities, were neither medically necessary, nor used for the care of the residents identified on the claims. In such a case, the supplier may be liable under criminal, civil and administrative laws for submitting fraudulent claims. The nursing facility may also be liable if the OIG determines that the nursing facility knew or should have known that the claims were false and participated in the offense.

Claims for Items That Are Not Provided as Claimed or Double Billed

- Many inappropriate transactions involve marketing of incontinence supplies. In one case, a supplier was found to have delivered adult diapers, which are not covered by Medicare Part B, and improperly billed these items as expensive prosthetic devices called “female external urinary collection devices.” In another case, a supplier delivered only incontinence care products, such as lubricants and cleansers. These items are covered only as accessories to medically necessary prosthetic devices such as female external urinary collection devices. Medicare received bills for each accessory, even though the primary item was not provided.

- In some cases, multiple payments are made for particular items shipped to nursing facilities. For instance, a nursing facility ordered and accepted delivery of certain medical supplies for the facility’s general use. The nursing facility appropriately claimed the supplies as expenses related to patient care on its Medicare cost report. However, the supplier also submitted separate claims to Medicare Part B on behalf of each resident in the facility. In order to receive Part B reimbursement, the supplier misrepresented its entitlement to payment, as well as the eligibility and coverage of individual beneficiaries. Other payment sources, such as Medicaid or private payers, may also have been billed by the supplier. The supplier may be liable under criminal, civil and administrative provisions if the supplier falsely stated the beneficiary met the required eligibility and coverage criteria. The nursing facility may also be liable for falsifying its Part A cost report if it knew or should have known of the duplicate billing and participated in the offense.
Paying or Receiving Kickbacks in Exchange for Medicare or Medicaid Referrals

It is illegal under the anti-kickback statute to knowingly and willfully solicit, receive, offer or pay remuneration in cash or in kind to induce or in return for referring, recommending or arranging for the furnishing of any item or service payable by Medicare or Medicaid.

Violation of the anti-kickback statute may carry criminal penalties, program exclusion, or both. Immunity may be available where otherwise illegal conduct meets the criteria specified in "safe harbor" regulations published by the Secretary of the Department of Health and Human Services. These regulations may be found in 42 CFR part 1001.

A supplier gives a nursing facility non-covered medical products at no charge, provided the facility assists in the ordering of Medicare-reimbursed products. For instance, incontinence care kits may consist of reimbursable supplies as well as non-reimbursable items, such as disposable underpads or adult diapers. The OIG has identified instances where suppliers have billed the program for providing nursing facilities with thousands of medical supplies contained within incontinence kits which were not medically necessary for the care of the patients. The nursing facilities accepted delivery of the kits, removed the diapers and other items useful in general patient care, and discarded the remainder of the kits. At the same time, the supplier received Medicare reimbursement for shipment of products which were not medically necessary and often not used.

Both the supplier and the nursing facility may be liable for false claims as in the previous examples. However, both parties may also be liable under the anti-kickback statute, if one purpose of providing the free diaper was to induce the nursing facility to arrange for the procurement of items paid for by Medicare or Medicaid.

Other Examples of Fraudulent Practices

The OIG has received many complaints from nursing facility administrators and staff about suppliers that deliver unordered goods which are billed to Medicare. Analysts and investigators also have found that many nursing facilities do not always report such abuses, perhaps because the nursing facilities may gain a benefit from the use of these "free" supplies. In other cases, nursing facilities actively solicit unauthorized deliveries or other items of value, such as cash and in-kind rewards. In exchange, the nursing facility offers the equipment supplier access to patients' medical records and other information needed to bill Medicare.

Note: Under 42 CFR 483.10(e), it is a violation of a resident's rights, and therefore of the facility's conditions of participation, to make unauthorized disclosures from the resident's medical records.

The OIG has investigated suppliers who supply nursing facilities with low-cost items, but submit Part B claims for high-priced items. For instance, one supplier provided simple restraining devices, but claimed that custom-made orthotic body jackets were provided to specified Part B beneficiaries.

The OIG also has investigated a case in which a supplier gathered information on the death of nursing facility residents. Immediately thereafter, the supplier back-dated orders of medical supplies in quantities consistent with Medicare's 30-day limitation on after-death shipments.

What To Look For in Nursing Facility Supply Transactions

Suppliers engaged in the fraudulent schemes described above attempt to avoid detection in a variety of ways. Nursing facility administrators and staff aware of supplier fraud may be bribed through the payment of kickbacks and other illegal remuneration. Also, beneficiaries may be kept unaware of fraudulent billings if a supplier routinely "waives," or fails to collect, co-payments from the residents for Part B items. The following factors may also indicate improper supply transactions:

- Excessive volumes of medical supplies delivered to, or solicited by, nursing facilities and kept as inventory for lengthy periods.
- Items provided directly to nursing facility residents that are unordered, unnecessary or unused.
- Unusually active presence in nursing facilities of medical supply sales representatives who are given, or request, unlimited access to patient medical records.
- Questionable documentation for medical necessity of supplies.

IV. Contacting the OIG About Fraud and Abuse

The following common language is set forth in both OIG Special Fraud Alerts:

What To do If You Have Information About Fraud and Abuse Against the Medicare and Medicaid Programs

If you have information about the types of activities described above, contact any of the regional offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

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<tr>
<th>Regions</th>
<th>States served</th>
<th>Telephone</th>
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<tbody>
<tr>
<td>Boston</td>
<td>MA, VT, NH, ME, RI, CT</td>
<td>617-565-2660</td>
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<tr>
<td>New York</td>
<td>NY, NJ, PR, VI</td>
<td>212-264-1691</td>
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<tr>
<td>Philadelphia</td>
<td>PA, MD, DE, WV, VA</td>
<td>215-596-6796</td>
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<tr>
<td>Atlanta</td>
<td>GA, KY, NC, SC, FL, TN, AL, MS (No. District)</td>
<td>404-331-2131</td>
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<tr>
<td>Chicago</td>
<td>IL, MN, WI, MI, IN, OH, IA, MO</td>
<td>312-353-2740</td>
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<tr>
<td>Dallas</td>
<td>TX, NM, OK, AR, LA, MS (So. District)</td>
<td>214-767-8406</td>
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<tr>
<td>Denver</td>
<td>CO, UT, WY, MT, ND, SD, NE, KS</td>
<td>303-844-5621</td>
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<tr>
<td>Los Angeles</td>
<td>AZ, NV (Clark Co.), So. CA</td>
<td>714-836-2372</td>
</tr>
<tr>
<td>San Francisco</td>
<td>No. CA, NV, AZ, HI, OR, ID, WA</td>
<td>415-556-8880</td>
</tr>
<tr>
<td>Washington, D.C.</td>
<td>DC and Metropolitan areas of VA &amp; MD</td>
<td>202-619-1900</td>
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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Nevada; Temporary Closure of Certain Public Lands in the Winnemucca District for Management of the 1995 Running of the "Reno 300" Off-Highway Vehicle (OHV) Race

AGENCY: Bureau of Land Management (Interior).

ACTION: Temporary closure of certain public lands in Washoe, Pershing, Churchill and Lyon Counties, Nevada on and adjacent to the 1995 "Reno 300" OHV race course on August 26, 1995. Access will be limited to race officials, entrants, law-enforcement and emergency personnel, licensed permittee(s) and right-of-way grantees.

SUPPLEMENTARY INFORMATION: Certain public lands in the Winnemucca District, Washoe, Lyon, Churchill and Pershing Counties will be temporarily closed to public access from 0600 hours, August 26, 1995 to 2400 hours, August 26, 1995, to protect persons, property and public land resources on and adjacent to the 1995 "Reno 300" OHV race course. The Sonoma-Gerlach Area Manager is the authorized officer for the 1995 "Reno 300" OHV race, permit number N2-21-95. These temporary closures and restrictions are made pursuant to 43 CFR Part 8364. The public lands to be closed or restricted are those lands adjacent to and including roads, trails and washes identified as the 1995 "Reno 300" OHV race course.

The following public lands administered by the BLM restricted or closed are described as the following: T. 21 N., R. 24 E., Sec. 36; T. 22 N., R. 24 E., Sec. 2, 10, 14 and 26; T. 23 N., R. 24 E., Sec. 9, 10, 12, 16, 17, 20, 22, 26, 28 and 34; T. 25 N., R. 24 E., Sec. 26; T. 24 N., R. 24 E., Sec. 4, 12, 14, 20, 22, 28 and 32; T. 22 N., R. 25 E., Sec. 18 and 30; T. 23 N., R. 25 E., Sec. 2, 10 and 12; T. 24 N., R. 25 E., Sec. 10, 22, 28 and 34; T. 25 N., R. 25 E., Sec. 28, 30, 31 and 34; T. 21 N., R. 26 E., Sec. 6; T. 22 N., R. 26 E., Sec. 2, 14, 22, 28 and 32; T. 23 N., R. 26 E., Sec. 4, 16, 22, 26 and 36; T. 24 N., R. 26 E., Sec. 28 and 32.

The lands involved are located in the Mount Diablo Meridian and are located north and northeast of Fernley, Nevada. They are within Washoe, Pershing, Churchill and Lyon Counties. A map showing the exact route of the course is available from the following BLM office: the Winnemucca District Office, 705 East Fourth Street, Winnemucca, Nevada, 89445, (702) 623-1500.

Any person who fails to comply with this closure order issued under 43 CFR Part 8364 may be subject to the penalties provided for in 43 CFR 8360.7.

FOR FURTHER INFORMATION CONTACT: Lynn Clemmons, 705 East Fourth Street, Winnemucca, Nevada 89445, (702) 623-1500.


Ron Wener,
District Manager, Winnemucca.

[FR Doc. 95-19707 Filed 8-9-95; 8:45 am]
BILLING CODE 4310-HC-P

[40851]

SUPPLEMENTARY INFORMATION: The subject lands have been segregated from the public land laws, including the mining and mineral leasing laws by submission of the State's application on July 6, 1995. The segregative effect of this Notice on the public lands shall end upon issuance of a clearlist or two years from the date of the application, whichever occurs first.


Sharon L. Sita,
Acting Ecosystem Manager.

[FR Doc. 95-19798 Filed 8-9-95; 8:45 am]
BILLING CODE 4310-GG-M

Fish and Wildlife Service

Availibility of a Draft Recovery Plan for the Washington, Oregon, and California Population of the Marbled Murrelet (Brachyramphus marmoratus marmoratus) for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces the availability for public review of a draft recovery plan for the threatened Marbled Murrelet, Brachyramphus marmoratus marmoratus. This species feeds primarily on fish and invertebrates...